ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Econor 50% premix for medicated feed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Econor 50% premix contains valnemulin in the form of valnemulin hydrochloride.

2.1 Active substance
Valnemulin hydrochloride      532.5 mg/g  
equivalent to     500 mg/g valnemulin base

2.2 Excipients knowledge of which is essential for the proper administration of the veterinary medicinal product
Hypromellose and talc

3. PHARMACEUTICAL FORM
Premix for medicated feed

4. PHARMACOLOGICAL PROPERTIES
Valnemulin is an antibiotic belonging to the pleuromutilin group, which acts by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome. Valnemulin has activity against a range of bacteria including those responsible for enteric and respiratory disease in pigs.

Valnemulin shows high activity against *Mycoplasma spp.* and spirochaetes such as *Serpulina hyodysenteriae*.

<table>
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<tr>
<th>Species</th>
<th>MIC (Range) (μg/ml)</th>
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<th>MIC(_{90}) (μg/ml)</th>
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<tr>
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Valnemulin has little activity against *Enterobacteriaceae*, such as *Salmonella spp.* and *Escherichia coli*.

In pigs, after a single oral dose of radiolabelled material >90% absorption was demonstrated. Maximum plasma concentrations (C\(_{max}\)) of radio-labelled or ‘cold’ material were obtained 1-4 hours after dosing (T\(_{max}\)) with a plasma half-life (t\(_{1/2}\)), estimated from non-radioactive data, between 1 and 4½ hours. A linear relationship between concentration and dose administered was established.

After repeat dosing, slight accumulation occurred, but a steady state was achieved within 5 days.
Because of a marked ‘first pass’ effect, plasma concentrations are affected by the method of administration, but valnemulin is highly concentrated in tissues, particularly the lungs and liver, relative to plasma. Five days after the last of 15 doses of radiolabelled valnemulin administered to pigs, the concentration in liver was >6 times that in plasma. Two hours after withdrawal of Premix given in feed twice daily for 4 weeks at a dose of 15 mg/kg/day, liver concentration was 1.58 μg/g and lung concentration 0.23 μg/g whereas concentrations in plasma were below the limit of detection.

In pigs valnemulin is extensively metabolised and excretion of parent molecule and metabolites occurs mainly via bile. 73% - 95% of the daily dose of total radioactivity was recovered from the faeces. The plasma half-life was 1.3 – 2.7 hours, and the majority of the total radio-activity administered was excreted within 3 days of the last administration.

5. CLINICAL PARTICULARS

5.1 Target species

Pigs

5.2 Indications for use, specifying the target species

Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 - 12 mg/kg bodyweight lung lesions and weight loss are reduced, but infection with *Mycoplasma hyopneumoniae* is not eliminated.

5.3 Contraindications

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

5.4 Undesirable effects (frequency and seriousness)

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs. Valnemulin is well-accepted in feed, but administered at concentrations above 200 ppm may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

5.5 Special precaution for use

None

5.6 Use during pregnancy and lactation

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety in pregnant and lactating sows has not been established.

5.7 Interaction with other veterinary medicinal products and other forms of interaction
Valnemulin has been shown to interact with the ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

5.8 Posology and method of administration

For oral use. The dosage is 10 – 12 mg/kg bodyweight per day. This is normally achieved, for example, in grower pigs, by incorporating Econor 50% at a level of 400 g/tonne feed to provide 200 mg active substance per kg feed depending on pigs’ feed intake.

\[ \text{Mg valnemulin base/kg feed} = \frac{\text{Dosage required (mg/kg)} \times 1,000 \times \text{bodyweight (kg)}}{\text{Daily feed intake (grams)}} \]

The medicated feed should be fed as the sole ration daily for up to 3 weeks. In older pigs, or in pigs with reduced appetite or on restricted feed intake, inclusion levels may need to be increased to achieve target dosage.

Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

**Mixing Instructions:**

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is highly recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 50% to 20 parts feed ingredient.

5.9 Overdose

Toxic signs have not been seen in pigs given 5 times the recommended dose.

5.10 Special warnings for each target species

None

5.11 Withdrawal period

4 days

5.12 Special precautions to be taken by the person administering the veterinary medicinal product to animals.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

6. PHARMACEUTICAL PARTICULARS
6.1 Incompatibilities

None known

6.2 Shelf life, when necessary after reconstitution of the veterinary medicinal product or when the container is opened for the first time

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

6.3 Special precautions for storage

Store below 25°C.
In case of aluminium-lined bags, store product in the original container.
In case of polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.
6.4 Nature and contents of container

1 kg and 25 kg low density polyethylene bags packed in cardboard carton or 1 kg and 25 kg aluminium-lined plastic bags.

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from such medicinal products, if appropriate

Any unused product or waste material should be disposed of in accordance with local requirements.

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Animal Health Austria GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

8. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

[leave blank]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[leave blank]

10. DATE OF REVISION OF THE TEXT

[leave blank]
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 10% premix for medicated feed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Econor 10% premix contains valnemulin in the form of valnemulin hydrochloride.

2.1 Active substance

Valnemulin hydrochloride 106.5 mg/g
equivalent to 100 mg/g valnemulin base

2.2 Excipients knowledge of which is essential for the proper administration of the veterinary medicinal product

Hypromellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PHARMACOLOGICAL PROPERTIES

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.

Valnemulin has activity against a range of bacteria including those responsible for enteric and respiratory disease in pigs.

Valnemulin shows high activity against Mycoplasma spp. and spirochaetes such as Serpulina hyodysenteriae.

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Valnemulin has little activity against Enterobacteriaceae, such as Salmonella spp. and Escherichia coli.

In pigs, after a single oral dose of radiolabelled material >90% absorption was demonstrated. Maximum plasma concentrations (C$_{max}$) of radiolabelled or ‘cold’ material were obtained 1-4 hours after dosing (T$_{max}$) with a plasma half-life (t½), estimated from non-radioactive data,
between 1 and 4½ hours. A linear relationship between concentration and dose administered was established.

After repeat dosing, slight accumulation occurred, but a steady state was achieved within 5 days.

Because of a marked ‘first pass’ effect, plasma concentrations are affected by the method of administration, but valnemulin is highly concentrated in tissues, particularly the lungs and liver, relative to plasma. Five days after the last of 15 doses of radiolabelled valnemulin administered to pigs, the concentration in liver was >6 times that in plasma. Two hours after withdrawal of Premix given in feed twice daily for 4 weeks at a dose of 15 mg/kg/day, liver concentration was 1.58 μg/g and lung concentration 0.23 μg/g whereas concentrations in plasma were below the limit of detection.

In pigs valnemulin is extensively metabolised and excretion of parent molecule and metabolites occurs mainly via bile. 73% - 95% of the daily dose of total radioactivity was recovered from the faeces. The plasma half-life was 1.3 – 2.7 hours, and the majority of the total radio-activity administered was excreted within 3 days of the last administration.

5. **CLINICAL PARTICULARS**

5.1 **Target species**

Pigs

5.2 **Indications for use, specifying the target species**

The treatment and prevention of swine dysentery. Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 – 12 mg/kg, lung lesions and weight loss are reduced, but infection with *Mycoplasma hyopneumoniae* is not eliminated..

5.3 **Contraindications**

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

5.4 **Undesirable effects (frequency and seriousness)**

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs.

Valnemulin is well accepted in feed, but administered at concentrations above 200 ppm may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

5.5 **Special precaution for use**

None

5.6 **Use during pregnancy and lactation**
Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety in pregnant and lactating sows has not been established.

5.7 Interaction with other veterinary medicinal products and other forms of interaction

Valnemulin has been shown to interact with the ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.
5.8 Posology and method of administration

For oral use.

**Treatment of swine dysentery:** The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 10% at a level of 750 g/tonne feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an outbreak of swine dysentery. In pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established.

**Prevention of swine dysentery:**
The dosage is 1 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 10% premix with the final feed at a level of 250 g/tonne feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

**Treatment and prevention of swine enzootic pneumonia:** The dosage is 10 – 12 mg/kg bodyweight per day. This is normally achieved, for example, in grower pigs, by incorporating Econor 10% at a level of 2 kg/tonne feed to provide 200 mg active substance per kg feed depending on pigs’ feed intake.

\[
\text{Mg valnemulin base / kg feed} = \text{Dosage required (mg/kg)} \times 1,000 \times \text{bodyweight (kg)} / \text{Daily feed intake (grams)}
\]

The medicated feed should be fed as the sole ration daily. In older pigs, or in pigs with reduced appetite or on restricted feed intake, inclusion levels may need to be increased to achieve target dosage.

Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

**Mixing Instructions:**
The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 10% Premix to 10 parts feed ingredient.

5.9 Overdose

Toxic signs have not been seen in pigs given 5 times the recommended dose.

5.10 Special warnings for each target species

None

5.11 Withdrawal period
4 days
5.12 Special precautions to be taken by the person administering the veterinary medicinal product to animals.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known

6.2 Shelf life, when necessary after reconstitution of the veterinary medicinal product or when the container is opened for the first time

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

6.3 Special precautions for storage

Store below 25°C.
In case of aluminium-lined bags, store product in the original container.
In case of polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

6.4 Nature and contents of container

1 kg and 25 kg low density polyethylene bags packed in cardboard carton or 1 kg and 25 kg aluminium-lined plastic bags.

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from such medicinal products, if appropriate

Any unused product or waste material should be disposed of in accordance with local requirements.

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10. DATE OF REVISION OF THE TEXT
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1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Econor 1% premix for medicated feed for pigs

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.

**Active substance**

Valnemulin hydrochloride 10.65 mg/g
equivalent to valnemulin base 10.0 mg/g

**List of excipients:**
Hypermellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. **PHARMACEUTICAL FORM**

Premix for medicated feed

4. **PHARMACOLOGICAL PROPERTIES**

4.1 **Pharmacodynamic properties:**

ATCvet code: QJ01XX94

Pharmacotherapeutic group: Antibacterial for systemic use

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.

Valnemulin has activity against a range of bacteria including those responsible for enteric and respiratory disease in pigs.

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Valnemulin has little activity against *Enterobacteriaceae*, such as *Salmonella spp.* and *Escherichia coli*.

4.2 **Pharmacokinetic properties:**
In pigs, after a single oral dose of radiolabelled material >90% absorption was demonstrated. Maximum plasma concentrations ($C_{\text{max}}$) of radiolabelled or ‘cold’ material were obtained 1-4 hours after dosing ($T_{\text{max}}$) with a plasma half-life ($t\frac{1}{2}$), estimated from non-radioactive data, between 1 and 4½ hours. A linear relationship between concentration and dose administered was established.

After repeat dosing, slight accumulation occurred, but a steady state was achieved within 5 days.

Because of a marked ‘first pass’ effect, plasma concentrations are affected by the method of administration, but valnemulin is highly concentrated in tissues, particularly the lungs and liver, relative to plasma. Five days after the last of 15 doses of radiolabelled valnemulin administered to pigs, the concentration in liver was >6 times that in plasma. Two hours after withdrawal of Premix given in feed twice daily for 4 weeks at a dose of 15 mg/kg bodyweight/day, liver concentration was 1.58 $\mu$g/g and lung concentration 0.23 $\mu$g/g whereas concentrations in plasma were below the limit of detection.

In pigs valnemulin is extensively metabolised and excretion of parent molecule and metabolites occurs mainly via bile. 73% - 95% of the daily dose of total radioactivity was recovered from the faeces. The plasma half-life was 1.3 – 2.7 hours, and the majority of the total radio-activity administered was excreted within 3 days of the last administration.

5. CLINICAL PARTICULARS

5.0 Target species

Pigs

5.1 Indications for use

The treatment and prevention of swine dysentery.

5.2 Contraindications

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

5.3 Undesirable effects

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs.

Valnemulin is well accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

5.4 Special precaution for use

None

5.5 Pregnancy and lactation
Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.
5.6 Interaction with other veterinary medicinal products and other forms of interaction

Valnemulin has been shown to interact with ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

5.7 Posology and method of administration

In-feed use.

Treatment of swine dysentery:
The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix at a level of 7.5 g/kg feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an outbreak of swine dysentery. In older pigs, or in pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Prevention of swine dysentery:
The dosage is 1.0 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix with the final feed at a level of 2.5 g/kg feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

Mixing Instructions:

mg Econor 1% premix/kg feed = Dosage required (mg/kg) x 100 x bodyweight (kg)/Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is incorporated at a rate less then 5 kg/tonne feed, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts feed ingredient.

5.8 Overdose

Toxic signs have not been seen in pigs given 5 times the recommended dose.

5.9 Special warnings for each target species

None
5.10 Withdrawal period
1 day

5.11 Special precautions to be taken by the person administering the veterinary medicinal product to animals.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities
None known

6.2 Shelf life

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

6.3 Special precautions for storage

Do not store above 25°C.
In case of aluminium-lined bags, store product in the original container.
In case of polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

6.4 Nature and contents of container

1 x 1 kg, 1 x 2.5 kg or 1 x 25 kg low density polyethylene bags packed in cardboard cartons or 1 kg, 2.5 kg and 25 kg aluminium-lined plastic bags.

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from such medicinal products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. PROHIBITION OF SALE, SUPPLY AND/OR USE

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
9. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/2/98/010/001-006

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12.03.1999

11. DATE OF REVISION OF THE TEXT

September 2000
ANNEX II

A. THE MANUFACTURING AUTHORITY(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORIZATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

D. STATEMENT OF THE MRLs
A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Manufacturer responsible for batch release in the EEA

Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
BP 224
68332 Huningue cedex
France

Manufacturing Authorisation issued on 04/07/97 by the Ministère de l’Agriculture, de la Pêche et de l’Alimentation, Ministère du Travail et des Affaires Sociales, France.

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

D. STATEMENT OF THE MRLs


<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRLs</th>
<th>Target tissues</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valnemulin(^{5})</td>
<td>Valnemulin</td>
<td>Porcine</td>
<td>100 µg/kg</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Liver</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>50 µg/kg</td>
<td>Muscle</td>
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<tbody>
<tr>
<td>Hypromellose(^{6})</td>
<td>All food-producing species</td>
<td></td>
</tr>
<tr>
<td>Purified Talc(^{7})</td>
<td>All food-producing species</td>
<td></td>
</tr>
<tr>
<td>Colloidal Anhydrous Silicia</td>
<td>All food-producing species</td>
<td></td>
</tr>
</tbody>
</table>

\(^{5}\) OJ No L 320 of 28.11.98
\(^{6}\) OJ No. L 272 of 25.10.96
\(^{7}\) OJ No. L 272 of 25.10.96
ANNEX III
LABELLING AND PACKAGE INSERT

In accordance with Article 48 of Council Directive 81/851/EEC the inclusion of a Package Insert in the packaging of the veterinary medicinal product shall not be obligatory, as all the information required is conveyed on the container or the outer package of the veterinary medicinal product.
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 50% premix for medicated feed

2. STATEMENT OF THE ACTIVE SUBSTANCE

Econor 50% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride  532.5 mg/g
equivalent to                500 mg/g valnemulin base
Hypromellose and talc

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PACKAGE SIZE

1 kg

5. TARGET SPECIES

Pigs

6. INDICATIONS

Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 - 12 mg/kg bodyweight lung lesions and weight loss are reduced, but infection with *Mycoplasma hyopneumoniae* is not eliminated.

7. DOSAGE FOR EACH SPECIES

The dosage is 10 – 12 mg/kg bodyweight per day.

8. METHOD AND ROUTE OF ADMINISTRATION

For oral use.

9. ADVICE ON CORRECT ADMINISTRATION
For oral use. The dosage is 10 – 12 mg/kg bodyweight per day. This is normally achieved, for example, in grower pigs, by incorporating Econor 50% at a level of 400 g/tonne feed to provide 200 mg active substance per kg feed depending on pigs’ feed intake.

\[ \text{Mg valnemulin base/kg feed} = \frac{\text{Dosage required (mg/kg) \times 1,000 \times \text{bodyweight (kg)}}}{\text{Daily feed intake (grams)}} \]

The medicated feed should be fed as the sole ration daily for up to 3 weeks. In older pigs, or in pigs with reduced appetite or on restricted feed intake, inclusion levels may need to be increased to achieve target dosage.

Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

**Mixing Instructions:**

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is highly recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 50% to 20 parts feed ingredient.

### 10. CONTRA-INDICATIONS

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

### 11. UNDESIRABLE EFFECTS

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs.

Valnemulin is well-accepted in feed, but administered at concentrations above 200 ppm may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

### 12. WITHDRAWAL PERIOD

4 days

### 13. SPECIAL STORAGE CONDITIONS

Store below 25°C.
In case of aluminium-lined bags, store product in the original container.
In case of polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.
Shelf life:
3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.
14. **SPECIAL WARNINGS**

Valnemulin has been shown to interact with the ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety in pregnant and lactating sows has not been established.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

15. **EXPIRY DATE**

{month/year}

16. **THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

17. **THE WORDS “KEEP OUT OF THE REACH OF CHILDREN”**

Keep out of the reach of children.

18. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Any unused product or waste material should be disposed of in accordance with local requirements.

19. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Novartis Animal Health Austria GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

20. **DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED**

[leave blank]
21. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

[leave blank]

22. MANUFACTURER'S BATCH NUMBER

[leave blank]

23. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription. Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

24. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which acts by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome. For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 50% premix for medicated feed

2. STATEMENT OF THE ACTIVE SUBSTANCE

Econor 50% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride 532.5 mg/g
equivalent to 500 mg/g valnemulin base
Hypromellose and talc

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PACKAGE SIZE

25 kg

5. TARGET SPECIES

Pigs

6. INDICATIONS

Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 - 12 mg/kg bodyweight lung lesions and weight loss are reduced, but infection with Mycoplasma hyopneumoniae is not eliminated.

7. DOSAGE FOR EACH SPECIES

The dosage is 10 – 12 mg/kg bodyweight per day.

8. METHOD AND ROUTE OF ADMINISTRATION

For oral use.

9. ADVICE ON CORRECT ADMINISTRATION

For oral use. The dosage is 10 – 12 mg/kg bodyweight per day. This is normally achieved, for example, in grower pigs, by incorporating Econor 50% at a level of 400 g/tonne feed to provide 200 mg active substance per kg feed depending on pigs’ feed intake.
Mg valnemulin base/kg feed = Dosage required (mg/kg) X 1,000 X bodyweight (kg) / Daily feed intake (grams)
The medicated feed should be fed as the sole ration daily for up to 3 weeks. In older pigs, or in pigs with reduced appetite or on restricted feed intake, inclusion levels may need to be increased to achieve target dosage.

Secondary infection by organisms such as Pasteurella multocida and Actinobacillus pleuropneumoniae may complicate enzootic pneumonia and require specific medication.

**Mixing Instructions:**

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is highly recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 50% to 20 parts feed ingredient.

**10. CONTRA-INDICATIONS**

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**11. UNDESIRABLE EFFECTS**

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs. Valnemulin is well-accepted in feed, but administered at concentrations above 200 ppm may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

**12. WITHDRAWAL PERIOD**

4 days

**13. SPECIAL STORAGE CONDITIONS**

Store below 25°C.
In case of aluminium-lined bags, store product in the original container.
In case of polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

Shelf life:
3 years
3 months, when incorporated into meal feed and protected from light and moisture.  
3 weeks, when incorporated into pelleted feed and protected from light and moisture.
14. SPECIAL WARNINGS

Valnemulin has been shown to interact with the ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety in pregnant and lactating sows has not been established.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

15. EXPIRY DATE

{month/year}

16. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

17. THE WORDS “KEEP OUT OF THE REACH OF CHILDREN”

Keep out of the reach of children.

18. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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19. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Novartis Animal Health Austria GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

20. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

[leave blank]
21. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

[leave blank]

22. MANUFACTURER'S BATCH NUMBER

[leave blank]

23. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription. Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

24. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which acts by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome. For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
<table>
<thead>
<tr>
<th>Country</th>
<th>Company Name</th>
<th>Address</th>
<th>Phone Numbers</th>
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<tbody>
<tr>
<td>Belgique/België</td>
<td>NOVARTIS AGRO Benelux B.V.</td>
<td>Animal Health Sector</td>
<td>Tel.: 0031- (0) 165.547804(5)</td>
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<td>Danmark</td>
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<td>DK - 2100 Copenhagen</td>
<td>Tel.: 39 16 84 00</td>
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<td>Deutschland</td>
<td>Novartis Tiergesundheit GmbH GmbH</td>
<td>Industriestrasse 30-34</td>
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<td>Elláda</td>
<td>Novartis (Hellas) S.A.C.I</td>
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<td>GR - 15344 Athens</td>
<td>Tel.: (01) 66 66 612 13</td>
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<td>España</td>
<td>NOVARTIS Sanidad Animal, S.L.</td>
<td>Carrer de la Marina, 206</td>
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<td>E - 08013 Barcelona</td>
<td>Tel.: +34 93 306 4865</td>
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<td>France</td>
<td>NOVARTIS Santé Animale SA</td>
<td>14 Boulevard Richelieu</td>
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<td>F - 92845 Rueil Malmaison</td>
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<tr>
<td>Ireland</td>
<td>Novartis Agribusiness Ireland Limited Limited</td>
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<td>Novartis Animal Health S.p.A.</td>
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<td>I - 21040 Origgio (VA)</td>
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<td>Rua Castilho 5, S-19</td>
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<td>Tel.: (351-1) 355 20 80</td>
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<td>FIN - 02130 Espoo</td>
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<td>S - 427 50 Billdal</td>
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<td>United Kingdom</td>
<td>Novartis Animal Health (UK)</td>
<td>Whittlesford</td>
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<td>GB - Cambridge CB2 4QT</td>
<td>Tel.: 01223 833634</td>
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</table>
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 10% premix for medicated feed

2. STATEMENT OF THE ACTIVE SUBSTANCE

Econor 10% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride 106.5 mg/g equivalent to 100 mg/g valnemulin base

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PACKAGE SIZE

1 kg

5. TARGET SPECIES

Pigs

6. INDICATIONS

The treatment and prevention of swine dysentery.
Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 – 12 mg/kg, lung lesions and weight loss are reduced, but infection with *Mycoplasma hyopneumoniae* is not eliminated.

7. DOSAGE FOR EACH SPECIES

Treatment of swine dysentery: The dosage is 3 – 4 mg/kg bodyweight per day
Prevention of swine dysentery: The dosage is 1 – 1.5 mg/kg bodyweight per day
Treatment and prevention of swine enzootic pneumonia: The dosage is 10 – 12 mg/kg bodyweight per day

8. METHOD AND ROUTE OF ADMINISTRATION

For oral use

9. ADVICE ON CORRECT ADMINISTRATION
Treatment of swine dysentery: The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 10% at a level of 750 g/tonne feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an outbreak of swine dysentery. In pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Prevention of swine dysentery: The dosage is 1 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 10% premix with the final feed at a level of 250 g/tonne feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

Treatment and prevention of swine enzootic pneumonia: The dosage is 10 – 12 mg/kg bodyweight per day. This is normally achieved, for example, in grower pigs, by incorporating Econor 10% at a level of 2 kg/tonne feed to provide 200 mg active substance per kg feed depending on pigs’ feed intake.

Mg valnemulin base / kg feed = Dosage required (mg/kg) X 1,000 X bodyweight (kg) / Daily feed intake (grams)

The medicated feed should be fed as the sole ration daily. In older pigs, or in pigs with reduced appetite or on restricted feed intake, inclusion levels may need to be increased to achieve target dosage.

Secondary infection by organisms such as Pasteurella multocida and Actinobacillus pleuropneumoniae may complicate enzootic pneumonia and require specific medication.

Mixing Instructions:

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 10% Premix to 10 parts feed ingredient.

10. CONTRA-INDICATIONS

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS
On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs. Valnemulin is well accepted in feed, but administered at concentrations above 200 ppm may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

12. WITHDRAWAL PERIOD

4 days

13. SPECIAL STORAGE CONDITIONS

Store below 25°C.
In case of aluminium-lined bags, store product in the original container.
In case of polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

Shelf life:

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

14. SPECIAL WARNINGS

Valnemulin has been shown to interact with the ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety in pregnant and lactating sows has not been established.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

15. EXPIRY DATE

{month/year}

16. THE WORDS “FOR ANIMAL TREATMENT ONLY”
For animal treatment only.

17. THE WORDS “KEEP OUT OF THE REACH OF CHILDREN”

Keep out of the reach of children.

18. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused product or waste material should be disposed of in accordance with local requirements.
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Novartis Animal Health Austria GmbH  
Biochemiestrasse 10  
A-6250 Kundl  
Austria

20. **DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED**

[leave blank]

21. **NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

[leave blank]

22. **MANUFACTURER’S BATCH NUMBER**

[leave blank]

23. **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.  
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

24. **OTHER INFORMATION**

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.  
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Belgique/België
NOVARTIS AGRO Benelux B.V.
Animal Health Sector
Stepvelden 10
NL - 4704 Roosendaal
Tel.: 0031- (0) 165.547804(5)

Danmark
NOVARTIS Agri A/S
Sector Animal Health
Lyngbyvej 172
DK - 2100 Copenhagen
Tel.: 39 16 84 00

Deutschland
Novartis Tiergesundheit GmbH
GmbH
Industriestrasse 30-34
D-65760 Eschborn
Tel.: +6196/95 56-32

Ελλάδα
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Anthoussas - Attikis
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Tel.: (01) 66 66 612 13

España
NOVARTIS Sanidad Animal, S.L.
Carrer de la Marina, 206
E - 08013 Barcelona
Tel.: +34 93 306 4865

France
NOVARTIS Santé Animale SA
14 Boulevard Richelieu
F - 92845 Rueil Malmaison
Tel.: 01 55 47 87 15

Italia
Novartis Animal Health S.p.A.
Strada Statale 233 km 20,5
I - 21040 Origgio (VA)
Tel.: 02-96542886

Luxemburg
NOVARTIS AGRO Benelux B.V.
Animal Health Sector
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Tel.: 0031- (0) 165.547804(5)

Nederland
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Animal Health Sector
Stepvelden 10
NL – 4704 Roosendaal
Tel.: 0 165.547804(5)

Österreich
NOVARTIS Animal Health
Biochemiestrasse 10
A-6250 Kundl
Tel.: 0043-5338-200425

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Novartis AGRO, Lda
Rua Castilho 5, S-19
P - 1250 Lisboa
Tel.: (351-1) 355 20 80

Suomi/Finland
NOVARTIS Finland OY
Animal Health Sector
Metsänneidonkuja 10
FIN - 02130 Espoo
Puh. (09) 6133 2211

Sverige
NOVARTIS Sverige AB
Veterinärmedicin
Kungsporten 4A
S - 427 50 Billdal
Tel.: 031-93 95 47

United Kingdom
Novartis Animal Health (UK)
Whittlesford
GB - Cambridge CB2 4QT
Tel.: 01223 833634
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
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Econor 10% premix contains valnemulin in the form of valnemulin hydrochloride.
Valnemulin hydrochloride 106.5 mg/g
equivalent to 100 mg/g valnemulin base

3. PHARMACEUTICAL FORM
Premix for medicated feed

4. PACKAGE SIZE
25 kg

5. TARGET SPECIES
Pigs

6. INDICATIONS
The treatment and prevention of swine dysentery.
Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 – 12 mg/kg, lung lesions and weight loss are reduced, but infection with *Mycoplasma hyopneumoniae* is not eliminated.

7. DOSAGE FOR EACH SPECIES
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8. METHOD AND ROUTE OF ADMINISTRATION
For oral use

9. ADVICE ON CORRECT ADMINISTRATION
Treatment of swine dysentery: The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 10% at a level of 750 g/tonne feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an outbreak of swine dysentery. In pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Prevention of swine dysentery: The dosage is 1 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 10% premix with the final feed at a level of 250 g/tonne feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

Treatment and prevention of swine enzootic pneumonia: The dosage is 10 – 12 mg/kg bodyweight per day. This is normally achieved, for example, in grower pigs, by incorporating Econor 10% at a level of 2 kg/tonne feed to provide 200 mg active substance per kg feed depending on pigs’ feed intake.

\[
\text{Mg valnemulin base / kg feed} = \frac{\text{Dosage required (mg/kg)} \times 1,000 \times \text{bodyweight (kg)}}{\text{Daily feed intake (grams)}}
\]

The medicated feed should be fed as the sole ration daily. In older pigs, or in pigs with reduced appetite or on restricted feed intake, inclusion levels may need to be increased to achieve target dosage.

Secondary infection by organisms such as Pasteurella multocida and Actinobacillus pleuropneumoniae may complicate enzootic pneumonia and require specific medication.

Mixing Instructions:
The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 10% Premix to 10 parts feed ingredient.

10. CONTRA-INDICATIONS

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS
On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs.

Valnemulin is well accepted in feed, but administered at concentrations above 200 ppm may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.
12. WITHDRAWAL PERIOD

4 days

13. SPECIAL STORAGE CONDITIONS

Store below 25°C.
In case of aluminium-lined bags, store product in the original container.
In case of polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

Shelf life:

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

14. SPECIAL WARNINGS

Valnemulin has been shown to interact with the ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety in pregnant and lactating sows has not been established.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

15. EXPIRY DATE

{month/year}

16. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

17. THE WORDS “KEEP OUT OF THE REACH OF CHILDREN”

Keep out of the reach of children.
18. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused product or waste material should be disposed of in accordance with local requirements.

19. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Novartis Animal Health Austria GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

20. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

[leave blank]

21. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

[leave blank]

22. MANUFACTURER'S BATCH NUMBER

[leave blank]

23. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription. Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

24. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome. For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Belgique/België
NOVARTIS AGRO Benelux B.V.
Animal Health Sector
Stepvelden 10
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Tel.: 0031- (0) 165.547804(5)

Danmark
NOVARTIS Agri A/S
Sector Animal Health
Lyngbyvej 172
DK - 2100 Copenhagen
Tel.: 39 16 84 00

Deutschland
Novartis Tiergesundheit GmbH
GmbH
Industriestrasse 30-34
D-65760 Eschborn
Tel.: +6196/95 56-32

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Anthoussas - Attikis
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Tel.: +34 93 306 4865

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Tel.: 01 55 47 87 15

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NOVARTIS Finland OY
Animal Health Sector
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Sverige
NOVARTIS Sverige AB
Veterinärmedicin
Kungsporten 4A
S - 427 50 Billdal
Tel.: 031-93 95 47

United Kingdom
Novartis Animal Health (UK)
Whittlesford
GB - Cambridge CB2 4QT
Tel.: 01223 833634
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE (Aluminium lined plastic bag)

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Econor 1% premix for medicated feed for pigs

2. **STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES**

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valnemulin hydrochloride</td>
<td>10.65 mg/g</td>
</tr>
<tr>
<td>Equivalent to valnemulin base</td>
<td>10.00 mg/g</td>
</tr>
</tbody>
</table>

**List of excipients:**
- Hypromellose and talc
- Colloidal anhydrous silica
- Isopropyl myristate
- Lactose

3. **PHARMACEUTICAL FORM**

Premix for medicated feed

4. **PACKAGE SIZE**

1 kg

5. **TARGET SPECIES**

Pigs

6. **INDICATION(S)**

For the treatment and prevention of swine dysentery.

7. **DOSAGE, METHOD AND ROUTE OF ADMINISTRATION**

In-feed use

**Treatment of swine dysentery:**
The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix at a level of 7.5 g/kg feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an
outbreak of swine dysentery. In older pigs, or in pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established

Prevention of swine dysentery:
The dosage is 1.0 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix with the final feed at a level of 2.5 g/kg feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

8. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 1% premix/kg feed = Dosage required (mg/kg) x 100 x bodyweight (kg)/Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is incorporated at a rate less then 5 kg/tonne feed, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts feed ingredient.

9.  WITHDRAWAL PERIOD

1 day

10. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS:

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs. Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding If you notice any other side effects, please inform your veterinary surgeon.
12. SPECIAL WARNING(S)

Valnemulin has been shown to interact with ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

13. EXPIRY DATE

{month/year}

14. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store product in the original container.
Part-used containers should be tightly closed following dispensing.

Shelf life:

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

16. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

17. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.
18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing Authorisation holder:
Novartis Animal Health Austria GmbH
Biochemiestraße 10
A-6250 Kundl
Austria
Manufacturing Authorisation holder responsible for batch release in the EEA
Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
BP 224
68332 Huningue cedex
France

19. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS
EU/2/98/010/004

20. MANUFACTURER’S BATCH NUMBER
[leave blank]

21. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE
Veterinary medicinal product subject to prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

22. DATE ON WHICH THE TEXT WAS LAST REVISED
September 2000

23. OTHER INFORMATION
Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Belgique/België/Belgien
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Tel.: 0031 165 57480-4/5

Danmark
Novartis Healthcare A/S
Sector Animal Health
Lyngbyvej 172
DK - 2100 Copenhagen
Tel.: 39 16 84 00

Deutschland
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D-65760 Eschborn
Tel.: 06196 95 56 32

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Industrial Park
IRL - Waterford
Tel.: 051 377201

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NL - 4704 Roosendaal
Tel.: 0165 57480-4/5

Österreich
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United Kingdom
Novartis Animal Health UK Limited
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GB – Herts SG8 0SS
Tel.: 01 763 850 500
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE (Polyethylene bag packed in cardboard carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 1% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.
Valnemulin hydrochloride 106.5 mg/g
equivalent to valnemulin base 100 mg/g

List of excipients:
Hypromellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PACKAGE SIZE

1 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

The treatment and prevention of swine dysentery.

7. DOSAGE, METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use

Treatment of swine dysentery:
The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix at a level of 7.5 g/kg feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an
outbreak of swine dysentery. In older pigs, or in pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Prevention of swine dysentery:
The dosage is 1.0 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix with the final feed at a level of 2.5 g/kg feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

8. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 1% premix/kg feed = Dosage required (mg/kg) x 100 x bodyweight (kg)/Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is incorporated at a rate less than 5 kg/tonne feed, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts feed ingredient.

9. WITHDRAWAL PERIOD

1 day

10. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS:

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs.

Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding. If you notice any other side effects, please inform your veterinary surgeon.
12. **SPECIAL WARNING(S):**

Valnemulin has been shown to interact with ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

13. **EXPIRY DATE**

{month/year}

14. **SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.
Store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

**Shelf life:**

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

15. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

16. **THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

17. **THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”**

Keep out of the reach and sight of children.
18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing Authorisation holder:
Novartis Animal Health Austria GmbH
Biochemiestraße 10
A-6250 Kundl
Austria
Manufacturing Authorisation holder responsible for batch release in the EEA
Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
BP 224
68332 Huningue cedex
France

19. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS
EU/2/98/010/001

20. MANUFACTURER’S BATCH NUMBER
[leave blank]

21. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE
Veterinary medicinal product subject to prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

22. DATE ON WHICH THE TEXT WAS LAST REVISED
September 2000

23. OTHER INFORMATION
Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
**Belgique/ België/ Belgien**
Novartis Consumer Health B.V.
Animal Health Sector
Stepvelden 10
NL - 4704 Roosendaal
Tel.: 0031 165 57480-4/5

**Luxembourg/ Luxemburg**
Novartis Consumer Health B.V.
Animal Health Sector
Stepvelden 10
NL - 4704 Roosendaal
Tel.: 0031 165 57480-4/5

**Danmark**
Novartis Healthcare A/S
Sector Animal Health
Lyngbyvej 172
DK - 2100 Copenhagen
Tel.: 39 16 84 00

**Nederland**
Novartis Consumer Health B.V.
Animal Health Sector
Stepvelden 10
NL - 4704 Roosendaal
Tel.: 0165 57480-4/5

**Deutschland**
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Tel.: 06196 95 56 32

**Österreich**
NOVARTIS Animal Health GmbH
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Tel.: 01 6538-061/181

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P – 2710-444 Sintra
Tel.: 01 21 0008600

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Tel.: 93 306 4865

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**France**
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Tel.: 01 55 47 87 15

**Sverige**
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IRL - Waterford
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**Italia**
Novartis Animal Health S.p.A.
Strada Statale 233 km 20,5
I - 21040 Origgio (VA)
Tel.: 02 96542886
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE (Aluminium lined plastic bag)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 1% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.  
Valnemulin hydrochloride  10.65 mg/g  
equivalent to valnemulin base  10.00 mg/g

List of excipients:  
Hypromellose and talc  
Colloidal anhydrous silica  
Isopropyl myristate  
Lactose

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PACKAGE SIZE

2.5 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

For the treatment and prevention of swine dysentery.

7. DOSAGE, METHOD AND ROUTE OF ADMINISTRATION

In-feed use

Treatment of swine dysentery:
The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix at a level of 7.5 g/kg feed to provide 75 mg active substance per kg feed.  
This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an
outbreak of swine dysentery. In older pigs, or in pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Prevention of swine dysentery:
The dosage is 1.0 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix with the final feed at a level of 2.5 g/kg feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

8. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 1% premix/kg feed = Dosage required (mg/kg) x 100 x bodyweight (kg)/Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is incorporated at a rate less then 5 kg/tonne feed, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts feed ingredient.

9. WITHDRAWAL PERIOD

1 day

10. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS:

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs. Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding. If you notice any other side effects, please inform your veterinary surgeon.
12. SPECIAL WARNING(S)

Valnemulin has been shown to interact with ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

13. EXPIRY DATE

{month/year}

14. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store product in the original container.
Part-used containers should be tightly closed following dispensing.

Shelf life:

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

16. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

17. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.
18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing Authorisation holder:
Novartis Animal Health Austria GmbH
Biochemiestraße 10
A-6250 Kundl
Austria
Manufacturing Authorisation holder responsible for batch release in the EEA
Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
BP 224
68332 Huningue cedex
France

19. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/2/98/010/005

20. MANUFACTURER’S BATCH NUMBER

[leave blank]

21. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

22. DATE ON WHICH THE TEXT WAS LAST REVISED

September 2000

23. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE (Polyethylene bag packed in cardboard carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 1% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.
Valnemulin hydrochloride  106.5 mg/g
equivalent to valnemulin base  100 mg/g

List of excipients:
Hypromellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PACKAGE SIZE

2.5 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

The treatment and prevention of swine dysentery.

7. DOSAGE, METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use

Treatment of swine dysentery:
The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix at a level of 7.5 g/kg feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an
outbreak of swine dysentery. In older pigs, or in pigs with reduced appetite or on restricted feed, inclusion levels may need to be increased to achieve target dosage. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Prevention of swine dysentery:
The dosage is 1.0 – 1.5 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix with the final feed at a level of 2.5 g/kg feed to provide 25 mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks. Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

8. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 1% premix/kg feed = Dosage required (mg/kg) x 100 x bodyweight (kg)/Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is incorporated at a rate less then 5 kg/tonne feed, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts feed ingredient.

9. WITHDRAWAL PERIOD

1 day

10. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophore antibiotics. Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS:

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated feed, remove to clean dry surroundings and apply appropriate supportive symptomatic therapy in affected pigs. Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding. If you notice any other side effects, please inform your veterinary surgeon.
12. **SPECIAL WARNING(S):**

Valnemulin has been shown to interact with ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

13. **EXPIRY DATE**

{month/year}

14. **SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.
Store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

Shelf life:

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

15. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

16. **THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

17. **THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”**

Keep out of the reach and sight of children.
18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing Authorisation holder:
Novartis Animal Health Austria GmbH
Biochemiestraße 10
A-6250 Kundl
Austria
Manufacturing Authorisation holder responsible for batch release in the EEA
Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
BP 224
68332 Huningue cedex
France

19. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/2/98/010/002

20. MANUFACTURER’S BATCH NUMBER

[leave blank]

21. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

22. DATE ON WHICH THE TEXT WAS LAST REVISED

September 2000

23. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Belgique/België/Belgien
Novartis Consumer Health B.V.
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Stepvelden 10
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Tel.: 0031 165 57480-4/5

Danmark
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Sector Animal Health
Lyngbyvej 172
DK - 2100 Copenhagen
Tel.: 39 16 84 00

Deutschland
Novartis Tiergesundheit GmbH
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D-65760 Eschborn
Tel.: 06196 95 56 32

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Tel.: 02 96542886

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Tel.: 01 21 0008600

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Animal Health Sector
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Puh. 09 6133 2211

Sverige
NOVARTIS Sverige AB
Veterinärmedicin
S – 250 24 Helsingborg
Tel.: 42 15 60 66

United Kingdom
Novartis Animal Health UK Limited
Litlington, Nr Royston
GB – Herts SG8 0SS
Tel.: 01 763 850 500
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE (Aluminum lined plastic bag)

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Econor 1% premix for medicated feed for pigs

2. **STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES**

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride 106.5 mg/g
equivalent to valnemulin base 100 mg/g

List of excipients:
- Hypromellose and talc
- Colloidal anhydrous silica
- Isopropyl myristate
- Lactose

3. **PHARMACEUTICAL FORM**

Premix for medicated feed

4. **PACKAGE SIZE**

25 kg

5. **TARGET SPECIES**

Pigs

6. **INDICATION(S)**

The treatment and prevention of swine dysentery.

7. **DOSAGE, METHOD AND ROUTE(S) OF ADMINISTRATION**

In-feed use

Treatment of swine dysentery:
The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix at a level of 7.5 g/kg feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an outbreak of swine dysentery. In older pigs, or in pigs with reduced appetite or on restricted
feed, inclusion levels may need to be increased to achieve target dosage. If there is no
response to treatment within 5 days, the diagnosis should be re-established

Prevention of swine dysentery:
The dosage is 1.0 – 1.5 mg/kg bodyweight per day. This is normally achieved by
incorporating Econor 1% premix with the final feed at a level of 2.5 g/kg feed to provide 25
mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for
a minimum of 7 days and up to 4 weeks. Long term preventative use of valnemulin should be
avoided by improving management practice and thorough cleansing and disinfection.
Consideration should be given to the eradication of infection from the farm.

8. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 1% premix/kg feed = Dosage required (mg/kg) x 100 x bodyweight (kg)/Daily
feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C.
Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of
abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is
incorporated at a rate less then 5 kg/tonne feed, the use of a pre-mixture is recommended.
The required quantity of product is thoroughly mixed with a feed ingredient of similar
physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts
feed ingredient.

9. WITHDRAWAL PERIOD

1 day

10. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophore antibiotics.
Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS:

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following
the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated
feed, remove to clean dry surroundings and apply appropriate supportive symptomatic
therapy in affected pigs.
Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg
feed may result in transient reduction in food consumption associated with unpalatability
during the first few days of feeding If you notice any other side effects, please inform your
veterinary surgeon.

12. SPECIAL WARNING(S):
Valnemulin has been shown to interact with ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

13. EXPIRY DATE

\{month/year\}

14. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store product in the original container.
Part-used containers should be tightly closed following dispensing.

Shelf life:

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

16. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

17. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.
18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing Authorisation holder:
Novartis Animal Health Austria GmbH
Biochemiestraße 10
A-6250 Kundl
Austria
Manufacturing Authorisation holder responsible for batch release in the EEA
Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
BP 224
68332 Huningue cedex
France

19. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS
EU/2/98/010/006

20. MANUFACTURER’S BATCH NUMBER
[leave blank]

21. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE
Veterinary medicinal product subject to prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

22. DATE ON WHICH THE TEXT WAS LAST REVISED
September 2000

23. OTHER INFORMATION
Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Belgique/België/Belgien
Novartis Consumer Health B.V.
Animal Health Sector
Stepvelden 10
NL - 4704 Roosendaal
Tel.: 0031 165 57480-4/5

Danmark
Novartis Healthcare A/S
Sector Animal Health
Lyngbyvej 172
DK - 2100 Copenhagen
Tel.: 39 16 84 00

Deutschland
Novartis Tiergesundheit GmbH
Industriestraße 30-34
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Tel.: 06196 95 56 32

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Premier Shukuroglou Hellas SA
S.A.
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Tel.: 01 6538-061/181

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Carrer de la Marina, 206
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Tel.: 93 306 4865

France
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Tel.: 02 96542886

Luxembourg/Luxemburg
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Animal Health Sector
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Tel.: 0031 165 57480-4/5

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D-65760 Eschborn
Tel.: 06196 95 56 32

Österreich
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A-6250 Kundl
Tel.: 05338 200425

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S.A.
Mesogion 198
GR - 15561 Holargos / Athens
Tel.: 01 6538-061/181

Suomi/Finland
NOVARTIS Finland OY
Animal Health Sector
Metsänneidonkuja 10
FIN - 02130 Espoo
Tel.: 09 6133 2211

Sverige
NOVARTIS Sverige AB
Veterinärmedicin
S – 250 24 Helsingborg
Tel.: 42 15 60 66

United Kingdom
NOVARTIS Animal Health UK Limited
Litlington, Nr Royston
GB – Herts SG8 0SS
Tel.: 01 763 850 500
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 1% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.
Valnemulin hydrochloride  106.5 mg/g
equivalent to valnemulin base  100 mg/g

List of excipients:
Hypromellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. PACKAGE SIZE

25 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

The treatment and prevention of swine dysentery.

7. DOSAGE, METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use

Treatment of swine dysentery:
The dosage is 3 – 4 mg/kg bodyweight per day. This is normally achieved by incorporating Econor 1% premix at a level of 7.5 g/kg feed to provide 75 mg active substance per kg feed. This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. The medicated feed should be fed as the sole ration daily for a minimum of 7 days and up to 4 weeks or until signs of disease disappear. It is important to institute medication as early as possible in an
outbreak of swine dysentery. In older pigs, or in pigs with reduced appetite or on restricted
feed, inclusion levels may need to be increased to achieve target dosage. If there is no
response to treatment within 5 days, the diagnosis should be re-established

Prevention of swine dysentery:
The dosage is 1.0 – 1.5 mg/kg bodyweight per day. This is normally achieved by
incorporating Econor 1% premix with the final feed at a level of 2.5 g/kg feed to provide 25
mg active substance per kg feed. The medicated feed should be fed as the sole ration daily for
a minimum of 7 days and up to 4 weeks. Long term preventative use of valnemulin should be
avoided by improving management practice and thorough cleansing and disinfection.
Consideration should be given to the eradication of infection from the farm.

8. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

\[
\text{mg Econor 1% premix/kg feed} = \text{Dosage required (mg/kg) x 100 x bodyweight (kg)/Daily feed intake (kg)}
\]

The product has been shown to be stable to the pelleting process at temperatures of 75°C.
Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of
abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is
incorporated at a rate less then 5 kg/tonne feed, the use of a pre-mixture is recommended.
The required quantity of product is thoroughly mixed with a feed ingredient of similar
physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts
feed ingredient.

9. WITHDRAWAL PERIOD

1 day

10. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophore antibiotics.
Valnemulin should not be administered to rabbits because of its toxicity in this species.

11. UNDESIRABLE EFFECTS:

On rare occasions perianal erythema or mild oedema of the skin may occur in pigs following
the use of valnemulin. If such signs are seen, immediately withdraw all remaining medicated
feed, remove to clean dry surroundings and apply appropriate supportive symptomatic
therapy in affected pigs.
Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg
feed may result in transient reduction in food consumption associated with unpalatability
during the first few days of feeding If you notice any other side effects, please inform your
veterinary surgeon.
12. SPECIAL WARNING(S):

Valnemulin has been shown to interact with ionophore antibiotics such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

13. EXPIRY DATE

{month/year}

14. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store the product in the original container within the outer carton and protected from light and moisture.
Part-used containers should be tightly closed following dispensing.

Shelf life:

3 years
3 months, when incorporated into meal feed and protected from light and moisture.
3 weeks, when incorporated into pelleted feed and protected from light and moisture.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

16. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

17. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.
18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing Authorisation holder:
Novartis Animal Health Austria GmbH
Biochemiestraße 10
A-6250 Kundl
Austria
Manufacturing Authorisation holder responsible for batch release in the EEA
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Usine de Huningue
26, rue de la Chapelle
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68332 Huningue cedex
France

19. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS
EU/2/98/010/003

20. MANUFACTURER’S BATCH NUMBER
[leave blank]

21. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE
Veterinary medicinal product subject to prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

22. DATE ON WHICH THE TEXT WAS LAST REVISED
September 2000

23. OTHER INFORMATION
Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Belgique/België/Belgien
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