

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pexion 100 mg tablets for dogs

Pexion 400 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active substance:

Imepitoin 100 mg

Imepitoin 400 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

White, oblong, half-scored tablets with embedded logo “I 01” (100 mg) or “I 02” (400 mg) on one side.

The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the target species

For the reduction of the frequency of generalised seizures due to idiopathic epilepsy in dogs for use after careful evaluation of alternative treatment options.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs with severely impaired hepatic function, severe renal or severe cardiovascular disorders (see section 4.7).

4.4 Special warnings

The pharmacological response to imepitoin may vary and efficacy may not be complete. Nevertheless imepitoin is considered to be a suitable treatment option in some dogs because of its safety profile (see section 5.1). On treatment, some dogs will be free of seizures, in other dogs a reduction of the number of seizures will be observed, whilst others may be non-responders. In non-responders, an increase in seizure frequency may be observed. Should seizures not be adequately controlled, further diagnostic measures and other antiepileptic treatment should be considered.

The benefit/risk assessment for the individual dog should take into account the details in the product literature.

The efficacy of the veterinary medicinal product in dogs with status epilepticus and cluster seizures has not been investigated. Therefore, imepitoin should not be used as primary treatment in dogs with cluster seizures and status epilepticus. Transition to other types of antiepileptic therapy should be done gradually and with appropriate clinical supervision.

No loss of anticonvulsant efficacy (tolerance development) during continuous treatment of 4 weeks was observed in experimental studies lasting 4 weeks.

4.5 Special precautions for use

Special precautions for use in animals

The safety of the veterinary medicinal product has not been tested in dogs weighing less than 5 kg or in dogs with safety concerns such as renal, liver, cardiac, gastrointestinal or other disease.

The efficacy as an add-on therapy has not been demonstrated.

Mild behavioural or muscular signs may be observed in dogs upon abrupt termination of treatment with imepitoin.

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

In case of accidental ingestion especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

To prevent accidental ingestion of tablets, the cap of the bottle should be replaced immediately after withdrawing the required number of tablets for one administration.

4.6 Adverse reactions (frequency and seriousness)

The following mild and generally transient adverse reactions have been observed in pre-clinical and clinical studies (in order of decreasing frequency): In rare cases polyphagia was reported at the beginning of the treatment, also hyperactivity, polyuria, polydipsia, somnolence, hypersalivation, emesis, ataxia, apathy, diarrhoea, prolapsed nictitating membrane, decreased sight and sensitivity to sound.

A mild elevation in plasma creatinine and cholesterol levels has been observed in dogs treated with imepitoin; however these did not exceed the normal reference ranges and were not associated with any clinically significant observations or events.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The use of the veterinary medicinal product is not recommended in male breeding dogs or in female dogs during pregnancy and lactation (see section 4.10).

4.8 Interaction with other medicinal products and other forms of interaction

The product has been used in combination with phenobarbital in a small number of cases and no harmful clinical interactions were observed.

4.9 Amounts to be administered and administration route

Oral administration at a dose range of 10 mg to 30 mg imepitoin per kg bodyweight twice daily, approximately 12 hours apart. Each tablet can be halved for appropriate dosing according to the individual bodyweight of the dog. Any remaining half-tablet should be used for the next dose.

The required dose will vary between dogs and will depend on the severity of the disorder. The recommended initial dose of imepitoin is 10 mg per kg bodyweight twice daily.

Initiate therapy using the bodyweight in kg and the dosing table. If seizures are not adequately reduced following a minimum of 1 week of treatment at the current dose the supervising veterinary surgeon should re-assess the dog. Assuming that the veterinary medicinal product is well tolerated by the dog, the dose can be increased by 50 to 100% increments up to a maximum dosage of 30 mg per kg administered twice daily.

Bioavailability is greater when administered to fasted dogs. The timing of tablet administration in relation to feeding should be kept consistent.

Number of tablets (to be given twice daily) for initiation of treatment:

Bodyweight (kg)	Number of tablets	
	100 mg tablet	400 mg tablet
2.0–5.0	½	
5.1–10.0	1	
10.1–15.0	1 ½	
15.1–20.0		½
20.1–40.0		1
40.1–60.0		1 ½
Over 60		2

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of repeated overdose of up to 5 times the highest recommended dose, central nervous system (CNS), gastrointestinal-related effects and reversible prolongation of the QT interval have been noted. At such doses, the symptoms are not usually life-threatening and generally resolve within 24 hours if symptomatic treatment is given.

These CNS effects may include loss of righting reflex, decreased activity, eyelid closure, lacrimation, dry eye and nystagmus.

At 5 times the recommended dose, decreased bodyweight may be observed.

In male dogs administered 10 times the upper recommended therapeutic dose, diffuse atrophy of seminiferous tubules in the testes and associated decreased sperm counts were seen. See also section 4.7.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiepileptics Other antiepileptics imepitoïn
ATCvet code: QN03AX90

5.1 Pharmacodynamic properties

Imepitoïn is a centrally acting antiepileptic substance which crosses the blood brain barrier without involvement of active transport or active clearance, resulting in immediate equilibrium between plasma and brain. Here it acts as a low affinity partial agonist of the benzodiazepine receptor.

Imepitoïn inhibits seizures via potentiation of the GABA_A receptor-mediated inhibitory effects on the neurons. In addition, imepitoïn has a weak calcium channel blocking effect which may contribute to its anticonvulsive properties.

In a European field trial that compared the efficacy of imepitoïn to phenobarbital in 226 dogs with newly diagnosed idiopathic epilepsy, 45% of cases from the imepitoïn group and 20% from the phenobarbital group were excluded from the efficacy analysis for reasons that included failure to respond to treatment. In the remaining dogs (64 dogs for Pexion and 88 dogs for phenobarbital), the following clinical results were observed: Mean frequency of generalised seizures was reduced from 2.3 seizures per month in the imepitoïn group and from 2.4 seizures per month in the phenobarbital group to 1.1 seizures per month in both groups after 20 weeks of treatment. The difference between imepitoïn and phenobarbital groups in the seizure frequency per month after treatment (adjusted for baseline difference) was 0.004, 95% CI [-0.928, 0.935]. During the evaluation phase of 12 weeks, the proportion of generalised seizure-free dogs was 47% (30 dogs) in the imepitoïn group and 58% (51 dogs) in the phenobarbital group.

The safety of both treatments was evaluated in the full analysis data set (or safety data set, i.e. 116 animals in the imepitoïn group and 110 animals in the phenobarbital group). Increasing doses of phenobarbital were associated with increasing levels of the liver enzymes ALT, AP, AST, GGT, and GLDH. In comparison, none of the five enzymes increased with increasing doses of imepitoïn. A slight increase in creatinine values compared to baseline was observed in the imepitoïn-treated dogs. However, the upper limit of the confidence interval for creatinine remained within the reference range at all visits. Additionally, fewer adverse events were noted for polyuria (10% vs 19% of dogs), polydipsia (14% vs 23%) and marked sedation (14% vs 25 %) when comparing imepitoïn to phenobarbital. Please refer to section 4.6 of the SPC for further details of adverse reactions.

5.2 Pharmacokinetic particulars

Absorption

Pharmacokinetic studies indicate that imepitoïn is well absorbed (> 92 %) after oral administration and that no pronounced first pass effect occurs. After oral administration of imepitoïn tablets at 30 mg/kg without food, peak blood concentrations are attained rapidly with a T_{max} of around 2 hours, a C_{max} of about 18 µg/ml. Co-administration of imepitoïn tablets with food, reduces the total AUC by 30% but produces no significant change in T_{max} and C_{max}. Gender-specific differences do not occur.

Distribution

Dose linearity occurs over the therapeutic dose range of imepitoïn.

Imepitoïn has a relatively high volume of distribution (579 to 1548 ml/kg). The *in-vivo* plasma protein binding of imepitoïn in dogs is low (60 to 70%). No interaction with highly protein bound compounds is therefore expected. No accumulation of imepitoïn in plasma occurs after repeated administration, once steady state is reached.

Metabolism

Imepitoin is extensively metabolised prior to elimination. Metabolite profiles in urine and faeces revealed four major inactive metabolites which are formed by oxidative modification.

Elimination

Imepitoin is rapidly cleared from blood (Cl = 260 to 568 ml/hours/kg) with an elimination half-life of approximately 1.5 to 2 hours. The majority of imepitoin and its metabolites are excreted via the faecal route rather than the urinary route so that no major change in pharmacokinetics and no accumulation is expected in renally impaired dogs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose microcrystalline
Hypromellose
Magnesium stearate
Sodium starch glycolate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 8 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Cardboard box containing 1 high-density polyethylene bottle of 100 or 250 tablets with a child resistant closure and a desiccant canister.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

8. MARKETING AUTHORISATION NUMBERS

EU/X/XX/XXX/XXX 100 tablets

EU/X/XX/XXX/XXX 250 tablets

EU/X/XX/XXX/XXX 100 tablets

EU/X/XX/XXX/XXX 250 tablets

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pexion 100 mg tablets for dogs
Pexion 400 mg tablets for dogs
Imepitoin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Imepitoin 100 mg
Imepitoin 400 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE(S)

100 tablets
250 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

16. MARKETING AUTHORISATION NUMBERS

EU/X/XX/XXX/XXX 100 tablets
EU/X/XX/XXX/XXX 250 tablets
EU/X/XX/XXX/XXX 100 tablets
EU/X/XX/XXX/XXX 250 tablets

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pexion 100 mg tablets for dogs
Pexion 400 mg tablets for dogs
Imepitoin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Imepitoin 100 mg
Imepitoin 400 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

100 tablets
250 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only- to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Read the package leaflet before use.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

16. MARKETING AUTHORISATION NUMBERS

EU/X/XX/XXX/XXX 100 tablets
EU/X/XX/XXX/XXX 250 tablets
EU/X/XX/XXX/XXX 100 tablets
EU/X/XX/XXX/XXX 250 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Pexion 100 mg tablets for dogs

Pexion 400 mg tablets for dogs

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

Marketing authorisation holder and manufacturer

Boehringer Ingelheim Vetmedica GmbH

55216 Ingelheim/Rhein

Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pexion 100 mg tablets for dogs

Pexion 400 mg tablets for dogs

Imepitoin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

White, oblong, half-scored tablets with embedded logo “I 01” (100 mg) or “I 02” (400 mg) on one side. The tablet can be divided into equal halves.

One tablet contains:

Imepitoin 100 mg

Imepitoin 400 mg

4. INDICATION(S)

For the reduction of the frequency of generalised seizures due to idiopathic epilepsy in dogs for use after careful evaluation of alternative treatment options.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs with severely impaired hepatic function, severe renal or severe cardiovascular disorders. See also section “Use during pregnancy or lactation”.

6. ADVERSE REACTIONS

The following mild and generally transient adverse reactions have been observed in pre-clinical and clinical studies (in order of decreasing frequency): In rare cases polyphagia (increased appetite) at the beginning of the treatment, also hyperactivity (much more active than usual), polyuria (increased urine production), polydipsia (increased thirst), somnolence (drowsiness), hypersalivation (increase saliva production), emesis (vomiting), ataxia (loss of coordination), apathy, diarrhoea, prolapsed nictitating membrane (visible third eyelid), decreased sight and sensitivity to sound.

A mild elevation in plasma creatinine and cholesterol levels has been observed in dogs treated with imepitoin; however these did not exceed the normal reference ranges and were not associated with any clinically significant observations or events.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral administration at a dose range of 10 mg to 30 mg imepitoin per kg bodyweight twice daily, approximately 12 hours apart. Each tablet can be halved for appropriate dosing according to the individual bodyweight of the dog. Any remaining half-tablet should be used for the next dose.

The required dose will vary between dogs and will depend on the severity of the disorder. The recommended initial dose of imepitoin is 10 mg per kg bodyweight twice daily.

Initiate therapy using the bodyweight in kg and the dosing table. If seizures are not adequately reduced following a minimum of 1 week of treatment at the current dose the supervising veterinary surgeon should re-assess the dog. Assuming that the veterinary medicinal product is well tolerated by the dog, the dose can be increased by 50 to 100% increments up to a maximum dosage of 30 mg per kg administered twice daily.

Bioavailability is greater when administered to fasted dogs. The timing of tablet administration in relation to feeding should be kept consistent.

Number of tablets (to be given twice daily) for initiation of treatment:

Bodyweight (kg)	Number of tablets	
	100 mg tablet	400 mg tablet
2.0–5.0	½	
5.1–10.0	1	
10.1–15.0	1 ½	
15.1–20.0		½
20.1–40.0		1
40.1–60.0		1 ½
Over 60		2

9. ADVICE ON CORRECT ADMINISTRATION

Each tablet can be halved for accurate dosing according to the individual bodyweight of the dog.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use after the expiry date stated on the carton and the bottle after EXP.

Shelf life after first opening the bottle: 8 months.

12. SPECIAL WARNING(S)

Because of the nature of epilepsy, the pharmacological response to treatment may vary. Some dogs will be free of seizures, in other dogs a reduction of the number of seizures will be observed, whilst others may be non-responders. In non-responders, an increase in seizure frequency may be observed. Should seizures not be adequately controlled, further diagnostic measures and other antiepileptic treatment should be considered.

The benefit-risk assessment in individual dogs should take into account the details in the product literature.

The efficacy of the veterinary medicinal product in dogs with status epilepticus and cluster seizures has not been investigated. Therefore, imepitoin should not be used as primary treatment in dogs with cluster seizures and status epilepticus. Transition to other types of antiepileptic therapy should be done gradually and with appropriate clinical supervision.

No loss of anticonvulsant efficacy (tolerance development) during continuous treatment of 4 weeks were observed in experimental studies lasting 4 weeks.

Precautions for use in animals

The safety of the veterinary medicinal product has not been tested in dogs weighing less than 5 kg or in dogs with safety concerns such as renal, liver, cardiac, gastrointestinal or other disease.

Mild behavioural or muscular signs may be observed in dogs upon abrupt termination of treatment with imepitoin.

Precautions to be taken by the person administering the product

In case of accidental ingestion especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

To prevent accidental ingestion of tablets, the cap of the bottle should be replaced immediately after withdrawing the required number of tablets for one administration.

Use during pregnancy and lactation

The use of the veterinary medicinal product is not recommended in male breeding dogs or in female dogs during pregnancy and lactation. See also section "Overdose".

Interactions

The product has been used in combination with phenobarbital in a small number of cases and no harmful clinical interactions were observed.

Overdose

In case of repeated overdose of up to 5 times the highest recommended dose, neurological, gastrointestinal-related effects and reversible prolongation of the QT interval have been noted.

At such doses, the symptoms are not usually life threatening and generally resolve within 24 hours if symptomatic treatment is given.

These neurological effects may include loss of righting reflex (loss of balance), decreased activity, eyelid closure, lacrimation (excessive tears), dry eye (inadequate tears), and nystagmus (unusual eye movement).

At 5 times the recommended dose, decreased bodyweight may be observed.

In male dogs administered 10 times the upper recommended therapeutic dose, diffuse atrophy of seminiferous tubules in the testes and associated decreased sperm counts were seen.

See also section "Use during pregnancy and lactation".

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

15. OTHER INFORMATION

In a European field trial that compared the efficacy of imepitoin to phenobarbital in 226 dogs with newly diagnosed idiopathic epilepsy, 45% of cases from the imepitoin group and 20% from the phenobarbital group were excluded from the efficacy analysis for reasons that included failure to respond to treatment. In the remaining dogs (64 dogs for Pexion and 88 dogs for phenobarbital), the following clinical results were observed: Mean frequency of generalised seizures was reduced from 2.3 seizures per month in the imepitoin group and from 2.4 seizures per month in the phenobarbital group to 1.1 seizures per month in both groups after 20 weeks of treatment. The difference between imepitoin and phenobarbital groups in the seizure frequency per month after treatment (adjusted for baseline difference) was 0.004, 95% CI [-0.928, 0.935]. During the evaluation phase of 12 weeks, the proportion of generalised seizure-free dogs was 47% (30 dogs) in the imepitoin group and 58% (51 dogs) in the phenobarbital group.

Though efficacy may not be complete, imepitoin is considered to be a suitable treatment option in some dogs because of its safety profile.

The safety of both treatments was evaluated in the full analysis data set (or safety data set, i.e. 116 animals in the imepitoin group and 110 animals in the phenobarbital group). Increasing doses of phenobarbital were associated with increasing levels of the liver enzymes ALT, AP, AST, GGT, and GLDH. In comparison, none of the five enzymes increased with increasing doses of imepitoin. A slight increase in creatinine values compared to baseline was observed in the imepitoin-treated dogs. However, the upper limit of the confidence interval for creatinine remained within the reference range at all visits. Additionally, fewer adverse events were noted for polyuria (10% vs 19% of dogs), polydipsia (14% vs 23%) and marked sedation (14% vs 25 %) when comparing imepitoin to phenobarbital. Please refer to section "Adverse reactions" for further details.

Package sizes:

Bottle of 100 or 250 tablets.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

België/Belgique/Belgien

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Avenue Ariane/Arianelaan 16
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Luxembourg/Luxemburg

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România

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Slovenija

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Slovenská republika

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