ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Altargo 1% ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains 10 mg retapamulin (1% w/w).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

Smooth, off-white ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Short term treatment of the following superficial skin infections:

Impetigo.

Infected small lacerations, abrasions, or sutured wounds.

See sections 4.4 and 5.1 for important information regarding the clinical activity of retapamulin against different types of *Staphylococcus aureus.*

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Retapamulin is for cutaneous use only.

Adults (aged 18-65 years), adolescents (aged 12-17 years), infants and children (aged from nine months to 11 years)

A thin layer of ointment should be applied to the affected area twice daily for five days. The area treated may be covered with sterile bandage or gauze dressing.

Safety and efficacy have not been established in the following:

- Impetiginous lesions >10 in number and exceeding 100 cm2 in total surface area.
- Infected lesions that exceed 10 cm in length or a total surface area >100 cm^2.

In patients aged less than 18 years the total surface area treated should be no more than 2% of the body surface area.

Patients not showing a clinical response within two to three days should be re-evaluated and alternative therapy should be considered (see section 4.4).

Infants under nine months of age

The safety and efficacy of retapamulin ointment has not been established in paediatric patients less than nine months of age.

Elderly (aged 65 and older)

No dosage adjustment is necessary.

Renal impairment

No dosage adjustment is necessary. See section 5.3.

Hepatic impairment

No dosage adjustment is necessary. See section 5.3.

4.3 Contraindications

Known or suspected hypersensitivity to retapamulin or to the excipient.

4.4 Special warnings and precautions for use

In the event of a sensitisation or severe local irritation from the use of retapamulin ointment, treatment should be discontinued, the ointment carefully wiped off, and appropriate alternative therapy for the infection instituted.

Retapamulin ointment must be kept away from the eyes and mucous membranes. Care must be taken to avoid ingestion.

Retapamulin should not be used to treat infections known or thought likely to be due to MRSA (see section 5.1).
In clinical studies of secondarily infected open wounds, the efficacy of retapamulin was inadequate in patients with infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA). The reason for the reduced clinical efficacy observed in these patients is unknown.

Alternative therapy should be considered if there is no improvement or a worsening in the infected area after 2-3 days of treatment.

Retapamulin should not be used to treat abscesses.

Retapamulin ointment contains butylated hydroxytoluene, which may cause local skin reaction (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

As with other antibacterial agents, prolonged use of retapamulin may result in overgrowth of non-susceptible micro-organisms, including fungi.

4.5 Interaction with other medicinal products and other forms of interaction

The effect of concurrent application of retapamulin and other topical products to the same area of skin has not been studied, and is not recommended.

In human liver microsomes, retapamulin was a strong inhibitor of CYP3A4. Based on the low plasma concentration achieved in humans after topical application to abraded skin or infected superficial wounds, a clinically relevant inhibition is not expected *in vivo* (see section 5.2)

Co-administration of oral ketoconazole 200mg twice daily increased mean retapamulin $AUC_{(0-24)}$ and C_{max} by 81% after topical application of retapamulin 1% ointment on the abraded skin of healthy adult males.
Due to low systemic exposure following topical application in patients, dosage adjustments are considered to be unnecessary when topical retapamulin is applied during systemic treatment with CYP3A4 inhibitors.

4.6 Pregnancy and lactation

Pregnancy
No clinical data on exposed pregnancies are available. Animal studies have shown reproductive toxicity after oral administration and are insufficient with respect to effects on parturition and fetal/postnatal development (see Section 5.3).

Retapamulin ointment should only be used in pregnancy when topical antibacterial therapy is clearly indicated and the use of retapamulin is considered to be preferable to administration of a systemic antibacterial agent.

Lactation
It is unknown whether retapamulin is excreted in human breast milk. Minimal systemic exposure is observed in adults, therefore exposure of the breast-feeding infant is likely to be negligible. The excretion of retapamulin in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Altargo should be made taking into account the benefit of breast-feeding to the child and the benefit of Altargo therapy to the woman.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Altargo is administered topically and is unlikely to have an effect on the ability to drive or use machines.

4.8 Undesirable effects

In clinical studies in which 2150 patients with superficial skin infections applied Altargo, the most commonly reported adverse reaction was application site irritation, which affected approximately 1% of patients.

The following convention has been used for the classification of frequency:

Common	$\geq$1/100 to <1/10
Uncommon	$\geq$1/1000 to <1/100
Not known	(cannot be estimated from the available data)

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Organ systems	Common	Uncommon	Unknown
General disorders and administration site conditions	Application site reactions Irritation	Application site reactions Pain Pruritus Erythema	Application site irritation (including burning sensation)
Skin and subcutaneous tissue disorders		Contact dermatitis	

4.9 Overdose

Any signs or symptoms of overdose, either topically or by accidental ingestion, should be treated symptomatically.
No specific antidote is known.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dermatologicals ATC code: D06AX13

Mode of action
Retapamulin is a semi-synthetic derivative of the compound pleuromutilin, which is isolated through fermentation from *Clitopilus passeckerianus* (formerly *Pleurotus passeckerianus*).

Retapamulin selectively inhibits bacterial protein synthesis by interacting at a unique site on the 50S subunit of the bacterial ribosome that is distinct from the binding sites of other non-pleuromutilin antibacterial agents that interact with the ribosome.

Data indicate that the binding site involves ribosomal protein L3 and is in the region of the ribosomal P site and peptidyl transferase centre. By virtue of binding to this site, pleuromutilins inhibit peptidyl transfer, partially block P-site interactions, and prevent normal formation of active 50S ribosomal subunits. Therefore the pleuromutilins appear to inhibit bacterial protein synthesis by multiple mechanisms.

Retapamulin is predominantly bacteriostatic against *S. aureus* and *S. pyogenes.*

Mechanism of Resistance

Due to its distinct mechanism of action, retapamulin does not demonstrate target specific cross-resistance with other classes of antibacterial agents.

In vitro, two mechanisms have been identified which reduce susceptibility to retapamulin. One involves mutations in ribosomal protein L3, the other is a non-specific efflux mechanism (ABC transporter *vgaAv*). This non-target specific efflux

mechanism has also been demonstrated to reduce the *in vitro* activity of streptogramin A.

No development of resistance was observed during treatment with retapamulin in the clinical study programme and all clinical isolates were inhibited by retapamulin concentrations of ≤2µg/ml.

Antibacterial spectrum

The prevalence of acquired resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infection is questionable.

Commonly susceptible species
*Staphylococcus aureus** [$]
*Streptococcus pyogenes**
Streptococcus agalactiae
Inherently resistant organisms
Enterobacteriaceae
Pseudomonas aeruginosa
Enterococcus faecalis

[$] *In vitro,* retapamulin was equally active against methicillin-susceptible and methicillin-resistant strains of *S. aureus*. However, see section 4.4 and below regarding clinical efficacy against MRSA. Retapamulin should not be used to treat infections known or thought likely to be due to MRSA.

* Activity has been satisfactorily demonstrated in clinical studies

Information from clinical trials

Very few MRSA were isolated in studies in impetigo and all were clinical successes (100%: 8/8)**.**
In studies in impetigo and in two studies of secondarily infected open wounds (SIOW), clinical success rates were high for retapamulin in patients with mupirocin-resistant *S. aureus* (100%: 11/11) or fusidic acid-resistant *S. aureus* (96.7%: 29/30). However, in the two studies that enrolled patients with SIOW the efficacy of retapamulin in infections due to MRSA was inadequate (75.7%). No differences were observed in the *in vitro* activity of retapamulin versus *S. aureus* whether the isolates were susceptible or resistant to methicillin.

The explanation for lower clinical efficacy against MRSA in SIOW is unclear and it may have been influenced by the presence of a particular MRSA clone. In the case of treatment failure associated with *S. aureus*, the presence of strains possessing additional virulence factors (such as Panton-Valentine Leukocidin) should be considered.

Clinical Success Rates at Follow up for SIOW patients with *S. aureus*

Phenotype/PFGE type	RETAPAMULIN			Cephalexin	
	n/N	Success Rate (%)	95% Exact CI	n/N	Success Rate (%)
S. aureus (all)	337/379	88.9	(85.3,91.9)	155/186	83.3
MRSA [$]	28/37	75.7	(58.8,88.2)	21/26	80.8
MSSA	309/342	90.4	(86.7,93.3)	133/159	83.6

CI: confidence interval. Exact CI is calculated using the F-distribution method.
[$]: the response rate for MRSA due to PVL+ MRSA was 8/13 (62%)

5.2 Pharmacokinetic properties

Absorption

In a study of healthy adult subjects, 1% retapamulin ointment was applied daily to intact and to abraded skin under occlusion for up to 7 days. Systemic exposure following topical application of retapamulin through intact skin was very low. The geometric mean C_{max} value in plasma after application to 200 cm^2 of abraded skin was 9.75 ng/ml on day 1 and 8.79 ng/ml on day 7 and the maximum individual systemic exposure (C_{max}) recorded was 22.1 ng/ml.

Single plasma samples were obtained from 516 adult and paediatric patients who received topical treatment with retapamulin 1% ointment twice daily for 5 days for the treatment of secondarily infected traumatic lesions. Sampling occurred pre-dose for adult subjects on days 3 or 4, and between 0-12 hours after the last application for paediatric subjects on days 3 or 4. The majority of samples (89%) were below the lower limit of quantitation (0.5 ng/ml). Of the samples that had measurable concentrations 90% had retapamulin concentrations less than 2.5 ng/ml. The maximum measured plasma concentration of retapamulin was 10.7 ng/ml in adults and 18.5 ng/ml in paediatric patients.

Distribution

Due to the very low systemic exposures, tissue distribution of retapamulin has not been investigated in humans.

In vitro, retapamulin was shown to be a P-glycoprotein (Pgp) substrate and inhibitor. However, the maximum individual systemic exposure in humans following topical application of 1% ointment on 200 cm^2 of abraded skin (C_{max}= 22 ng/ml; $AUC_{(0-24)}$ = 238 ng.h/ml) was 660-fold lower than the retapamulin IC_{50} for Pgp inhibition.

Retapamulin is approximately 94% bound to human plasma proteins.

Metabolism

The *in vitro* oxidative metabolism of retapamulin in human liver microsomes was primarily mediated by CYP3A4 with minor contributions from CYP2C8 and CYP2D6 (see section 4.5).

Elimination

Retapamulin elimination in humans has not been investigated.

Special Patient Populations

No pharmacokinetic data are available in children aged less than 2 years, or in patients with renal or hepatic impairment. However, due to the low systemic plasma levels that have been observed, no safety problems are foreseen.

5.3 Preclinical safety data

Repeated-dose toxicity

In 14-day (50, 150 or 450 mg/kg) oral toxicity studies in rats there was evidence of adaptive hepatic and thyroid changes. Neither of these findings is of clinical relevance.

In monkeys dosed orally (50, 150 or 450 mg/kg) for 14 days there was dose-related emesis.

Carcinogenesis, mutagenesis, reproductive toxicity

Long-term studies in animals to evaluate carcinogenic potential have not been conducted with retapamulin.

There was no evidence of genotoxicity when evaluated in *vitro* for gene mutation and/or chromosomal effects in the mouse lymphoma cell assay, in cultured human peripheral blood lymphocytes, or when evaluated *in vivo* for chromosomal effects in a rat micronucleus test.

There was no evidence of impaired fertility in male or female rats at oral doses of 50, 150, or 450 mg/kg/day, resulting in exposure margins of up to 5-times the highest human estimated exposure (topical application to 200 cm^2 abraded skin: AUC 238 ng.h/ml).

In an embryotoxicity study in rats, developmental toxicity (decreased fetal body weight and delayed skeletal ossification) and maternal toxicity were observed at oral doses of ≥ 150 mg/kg/day (corresponding to ≥ 3 times the human estimated exposure (see above). There were no treatment-related malformations in rats.

Retapamulin was given as a continuous intravenous infusion to pregnant rabbits from day 7 to day 19 of gestation. Maternal toxicity was demonstrated at dosages of ≥ 7.2 mg/kg/day corresponding to ≥ 8 times the estimated human exposure (see above). There was no treatment-related effect on embryo-fetal development.

No studies to evaluate effects of retapamulin on pre-/postnatal development were performed. However, there were no systemic effects on juvenile rats with topical application of retapamulin ointment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin.
Butylated hydroxytoluene

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years.

In-use: 7 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

0.5 g aluminium foil sachet. Carton of 12 sachets.

5 g, 10 g and 15 g aluminium tubes with a plastic screw cap. Carton of 1 tube.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any remaining ointment at the end of treatment should be discarded.

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

7. MARKETING AUTHORISATION HOLDER

Glaxo Group Ltd
Glaxo Wellcome House
Berkeley Avenue
Greenford
Middlesex UB6 0NN
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/07/390/001
EU/1/07/390/002
EU/1/07/390/003
EU/1/07/390/004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/05/2007

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicine is available on the European Medicines Agency (EMEA) web site: http://www.emea.europa.eu/.

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Glaxo Operations UK Ltd. (trdg as Glaxo Wellcome Operations)
Harmire Road
Barnard Castle
Durham, DL12 8DT
United Kingdom

B. CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable.

- **OTHER CONDITIONS**

Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance, as described in version 7.2 presented in Module 1.8.1. of the Marketing Authorisation Application, is in place and functioning before the product is placed on the market and for as long as the marketed product remains in use.

Risk Management plan

The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version 1 of the Risk Management Plan (RMP) presented in Module 1.8.2. of the Marketing Authorisation Application and any subsequent updates of the RMP agreed by the CHMP.

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted

- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities.
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached.
- At the request of the EMEA.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR 5 g, 10 g, 15 g TUBE

1. NAME OF THE MEDICINAL PRODUCT

Altargo 1% ointment
Retapamulin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 g contains: 10 mg retapamulin (1% w/w)

3. LIST OF EXCIPIENTS

Also contains:
White soft paraffin
E321
See package leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

ointment
5 g x 1 tube
10 g x 1 tube
15 g x 1 tube

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use only
Do not swallow
Apply to the affected area as directed by your doctor
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not use in the eyes or on mucous membranes

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Glaxo Group Ltd
Glaxo Wellcome House
Berkeley Avenue
Greenford
Middlesex UB6 0NN
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/07/390/002 5 g
EU/1/07/390/003 10 g
EU/1/07/390/004 15 g

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Altargo

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR 0.5 g SACHET

1. NAME OF THE MEDICINAL PRODUCT

Altargo 1% ointment
Retapamulin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 g contains: 10 mg retapamulin (1% w/w)

3. LIST OF EXCIPIENTS

Also contains:
White soft paraffin
E321
See package leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Ointment

0.5 g x 12 sachets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use only
Do not swallow
Apply to the affected area as directed by your doctor
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not use in the eyes or on mucous membranes

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Glaxo Group Ltd
Glaxo Wellcome House
Berkeley Avenue
Greenford
Middlesex UB6 0NN
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/07/390/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Altargo

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 g, 10 g 15 g TUBE

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Altargo 1% ointment
Retapamulin
Cutaneous use.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

5 g

10 g

15 g

6. OTHER

Do not use in the eyes or on mucous membranes

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

0.5 g SACHET

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Altargo 1% ointment
Retapamulin
Cutaneous use.

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 g

6. OTHER

Do not use in the eyes or on mucous membranes

Do not store above 25°C.

Read the package leaflet before use

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Altargo 1% ointment

Retapamulin

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms seem the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT ALTARGO IS AND WHAT IT IS USED FOR

Altargo is used to treat bacterial infections affecting small areas of skin. Infections that may be treated include impetigo (which causes crusting scabs on infected areas), cuts, grazes and stitched wounds.

Altargo is for adults and children aged nine months and older.

2. BEFORE YOU USE ALTARGO

Do not use Altargo:

If you are allergic (hypersensitive) to retapamulin or any of the other ingredients of Altargo.

Take special care with Altargo:

If you notice any worsening of the infection or develop increased redness, irritation or other signs and symptoms at the site of application you should stop using Altargo and tell your doctor. See also section 4 of this leaflet.

If there is no improvement in your infection after two to three days of treatment contact your doctor.

Using other medicines:

Do not apply other ointments, creams or lotions to the area being treated with Altargo unless specifically instructed to do so by your doctor.

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before using any medicine.

Do not use Altargo if you are pregnant, or planning to become pregnant. Ask your doctor or pharmacist for advice.
Do not use Altargo if you are breast-feeding a baby. Ask your doctor or pharmacist for advice.

3. HOW TO USE ALTARGO

Always use Altargo exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Altargo is for use on the skin only. It must not be put in the eyes, on the mouth or lips, inside the nose or inside the female genital area. If the ointment accidentally gets on to these areas, wash the area with water and consult your doctor if you experience discomfort.
Wash your hands before and after applying the ointment.

How to apply Altargo

A thin layer of ointment is usually put on the infected skin twice a day for five days.
After applying your ointment, you may cover the treated area with a sterile bandage or gauze dressing, unless your doctor has told you to leave it uncovered.
Keep using Altargo for as long as your doctor advises.

If you use too much Altargo

Carefully wipe off the extra ointment.

Problems with overdosage with this medicine are unlikely.

If you forget to use Altargo

Apply the ointment as soon as you remember, and apply the next dose at the usual time.

If you accidentally swallow Altargo

Contact your doctor or pharmacist for advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Altargo can cause side effects, although not everybody gets them.

These side effects have occurred on the skin where Altargo has been applied:

<u>Common side effects</u>
- skin irritation

This may affect up to 1 in 10 people.

<u>Uncommon side effects</u>
- pain, itching, redness or rash (contact dermatitis)

These may affect up to 1 in 100 people.

Other side effects

- a burning sensation

It is not known how many people this may affect.

Altargo contains butylated hydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

If you develop signs of a local reaction, such as itching, swelling, redness or pain where you have used Altargo: Tell your doctor.

If you have a severe reaction (e.g. severe itching or severe rash): Stop using Altargo, carefully wipe off the ointment, and contact your doctor or pharmacist immediately.

If any of the side effects gets serious, or if you notice any side-effects that are not mentioned in this leaflet: Tell your doctor or pharmacist.

5. HOW TO STORE ALTARGO

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use Altargo after the expiry date which is stated on the carton.
The expiry date refers to the last day of that month.

Discard open tubes 7 days after opening.
Return any unused Altargo to your pharmacist.

6. FURTHER INFORMATION

What Altargo contains

- The active substance is retapamulin.
- The other ingredients are white soft paraffin and butylated hydroxytoluene (E321), a preservative.

What Altargo looks like and contents of the pack

Altargo is a smooth, off-white ointment.
It is supplied in an aluminium tube with a plastic cap, containing either 5, 10 or 15 grams of ointment, or in an aluminium foil sachet containing 0.5 g of ointment.
Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Glaxo Group Ltd
Glaxo Wellcome House
Berkeley Avenue
Greenford
Middlesex UB6 0NN
United Kingdom

Manufacturer

Glaxo Operations UK, Ltd, (trading as Glaxo Wellcome Operations)
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