

[Version 8, 10/2012]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Malaseb shampoo for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substances:

Chlorhexidine digluconate 20 mg (equivalent to chlorhexidine 11.26 mg)

Miconazole nitrate 20 mg (equivalent to miconazole 17.37 mg)

Excipients:

Methylchloroisothiazolinone 0.0075 mg

Methylisothiazolinone 0.0025 mg

Sodium Benzoate 1.25 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Shampoo.

A clear to slightly unclear, light yellow to light brown liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs: For the treatment and control of seborrhoeic dermatitis associated with *Malassezia pachydermatis* and *Staphylococcus intermedius*.

Cats: As an aid in the treatment of ringworm due to *Microsporum canis* in conjunction with griseofulvin.

4.3 Contraindications

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

4.4 Special warnings for each target species

Dogs and cats:

In order to prevent reoccurrence of the infection, appropriate control methods should be employed in the animal's environment (e.g. cleaning and disinfection of kennels, beds).

Cats:

Malaseb shampoo should only be used in conjunction with griseofulvin when treating for ringworm.

Shampooing cats may initially increase the recovery of *M. canis* by brush culture techniques.

Both field and experimental studies have shown that environmental contamination with *M. canis* can be eliminated or reduced by the use of Malaseb shampoo twice weekly. In these studies, griseofulvin was administered continuously throughout the treatment period and both clinical improvement was enhanced and environmental contamination reduced compared to the use of griseofulvin alone.

4.5 Special precautions for use

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Special precautions for use in animals:

For external use only.

In case of accidental contact with eyes, rinse with plenty of water.

Do not allow the animal to lick itself during shampooing and rinsing, or before it is dried. Take care to avoid the animal inhaling the product or getting it into the nose or mouth during shampooing.

Puppies and kittens should not come into contact with nursing females after treatment until the coat has dried.

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

- People with known hypersensitivity to chlorhexidine, miconazole or any of the excipients should avoid contact with the veterinary medicinal product.
- This product can cause eye irritation. Avoid contact with the eyes. In case of accidental contact with eyes, rinse with plenty of water. If irritation persists consult your doctor.
- Avoid excessive handling and stroking of treated animals immediately following treatment.
- Ringworm in the cat is infectious to humans and so it is advisable to wear gloves and have arms covered during clipping and shampooing of infected cats.
- When shampooing a cat, in order to avoid prolonged contact with the shampoo, wash and dry hands gently. Do not scrub.

4.6 Adverse reactions (frequency and seriousness)

Exceptionally a dog with atopy or a cat with allergic skin disease may develop a pruritic and/or erythematous reaction after treatment.

In very rare circumstances, dogs and cats may develop a skin reaction (itching, redness) after treatment.

4.7 Use during pregnancy or lactation

Pregnancy:

Malaseb shampoo in conjunction with griseofulvin should not be used in pregnant cats as griseofulvin is contra-indicated in pregnancy.

Lactation:

Please see section 4.5.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dogs: As a general rule, shampoo twice weekly until the symptoms subside and weekly thereafter or as necessary to keep the condition under control.

Cats: Shampoo twice weekly for a minimum period until coat brushings are negative for the culture of *M. canis*. The maximum length of the treatment period should not exceed 16 weeks. Depending on the length and type of the haircoat it should be considered whether it is necessary to clip the haircoat of the cat prior to treatment.

Wet the animal thoroughly with clean water and apply Malaseb shampoo to the animal at several points and massage into the coat. Use a sufficient amount of the shampoo to raise a lather on the coat and skin. Ensure that the shampoo is applied around the lips, under the tail and between the toes. Allow the animal to stand for 10 minutes, then rinse off with clean water and leave to dry naturally in a warm, draught-free environment.

The 250 ml bottle, for example, provides approximately 8-16 treatments for a 15 kg dog, or 5-10 treatments for a 25 kg dog or 25 cat treatments, depending on coat thickness.

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

Not applicable.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals

ATCvet code: QD01AC52

5.1 Pharmacodynamic properties

Chlorhexidine digluconate:

Chlorhexidine digluconate is a Bisbiguanide antimicrobial agent against Gram-positive and Gram-negative bacteria. It is both bactericidal and bacteriostatic depending on the concentration used. Growth inhibition is achieved by a direct effect on ATP-ase so interfering with the energy transport mechanisms. The bactericidal effect of chlorhexidine results from coagulation of the bacterial cell contents.

Chlorhexidine digluconate is incorporated in the product for its activity against *Staphylococcus intermedius*. Typical MIC values found in clinical *Staphylococcus intermedius* isolates are 2.0 mg/l (2005). *Staphylococcus intermedius* resistance to chlorhexidine has not been reported.

Miconazole nitrate:

Miconazole nitrate is an imidazole antifungal agent with activity against yeasts such as *Malassezia pachydermatis*.

It is both fungicidal and fungistatic depending on the concentration used. Miconazole inhibits ergosterol incorporation into cell membranes so increasing concentrations of cytotoxic hydrogen peroxide within the fungal cell wall.

Miconazole nitrate has been incorporated in the product for its activity against *Malassezia pachydermatis*. Typical MIC values found in clinical *Malassezia pachydermatis* isolates are 0.5-4.0 mg/l (2003/5). *Malassezia pachydermatis* resistance to miconazole has not been reported.

Chlorhexidine and miconazole in combination:

In vitro studies have demonstrated synergistic activity against *Microsporum canis* between chlorhexidine and miconazole.

5.2 Pharmacokinetic particulars

Chlorhexidine digluconate:

High concentrations of chlorhexidine digluconate are achieved in the hair coat and on the skin for the 10 minute period following shampooing. These concentrations are well in excess of the MICs for *Staphylococcus intermedius*. Chlorhexidine digluconate is poorly absorbed from the gastrointestinal tract on ingestion. There is little or no percutaneous absorption. In humans, it has been shown that 26% remains on the skin at 29 hours after application.

Miconazole nitrate:

High concentrations of miconazole nitrate are achieved in the hair coat and on the skin for the 10 minute period following shampooing. These concentrations are well in excess of the MICs for *Malassezia pachydermatis*.

Miconazole nitrate is poorly absorbed from the skin and gastrointestinal tract.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylchloroisoithiazolinone
Methylisothiazolinone
Macrogol lauryl ether
Cocamidopropyl Betaine
Sodium Benzoate
Disodium cocoamphodiacetate
Cetrimonium chloride
PEG-120 methyl glucose dioleate
Citric acid monohydrate
Hydrochloric acid
Water, purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 3 months.

6.4 Special precautions for storage

Do not store above 30°C.
Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

The container is a 250 ml polyethylene bottle with a polypropylene screw cap.

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

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

8. MARKETING AUTHORISATION NUMBER

Vm 24883/4005
VPA 10803/005/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 November 2007

10. DATE OF REVISION OF THE TEXT

October 2013