1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Malaseb shampoo for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methylchloroisothiazolinone	0.0075 mg
Methylisothiazolinone	0.0025 mg
Sodium Benzoate	1.25 mg
Macrogol lauryl ether	
Cocamidopropyl Betaine	
Disodium cocoamphodiacetate	
Cetrimonium chloride	
PEG-120 methyl glucose dioleate	
Citric acid monohydrate	
Hydrochloric acid	
Water, purified	

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each 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.

3.3 Contraindications

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

3.4 Special warnings

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:
The veterinary medicinal product 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 the veterinary medicinal product 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

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 veterinary medicinal 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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site erythema[a], Application site pruritus[a] Skin reaction (itching, reddening of the skin)

[a] Exceptionally in dogs with atopy or cats with allergic skin disease.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The veterinary medicinal product in conjunction with griseofulvin should not be used in pregnant cats as griseofulvin is contra-indicated in pregnancy.
Please see section 3.5.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cutaneous use.

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 itis necessary to clip the haircoat of the cat prior to treatment.

Wet the animal thoroughly with clean water and apply the veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QD01AC52

4.2 Pharmacodynamics

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 veterinary medicinal 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 veterinary medicinal 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Veterinary Products A/S

7. MARKETING AUTHORISATION NUMBER(S)

VPA10803/005/001

8. DATE OF FIRST AUTHORISATION

16/01/2009

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).