

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Malaseb shampoo for dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Antibacterial and antifungal.

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.

3. PHARMACEUTICAL FORM

Shampoo

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

Not applicable.

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: {MM YYYY}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL 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

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

16. MARKETING AUTHORISATION NUMBER(S)

Vm 24883/4005
VPA 10803/005/001

17. MANUFACTURER'S BATCH NUMBER

Lot: {xxxxxx}

ANY OTHER INFORMATION:

POM-V Prescription Only Medicine – Veterinarian

POM Prescription Only Medicine

PACKAGE LEAFLET FOR:
Malaseb shampoo for dogs and cats

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE**

Marketing authorisation holder:

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

Manufacturer responsible for batch release:

Genera Inc.,
Svetonedeljska cesta 2,
Kalinovica,
10436 Rakov Potok,
Croatia

Dales Pharmaceuticals
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Malaseb shampoo for dogs and cats

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER
INGREDIENTS**

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.

The product is a clear to slightly unclear, light yellow to light brown liquid.

4. INDICATIONS

For the treatment and control of seborrhoeic dermatitis associated with *Malassezia pachydermatis* and *Staphylococcus intermedius* in dogs.
As an aid in the treatment of ringworm due to *Microsporum canis* in the cat in conjunction with griseofulvin.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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

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

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

7. TARGET SPECIES

Dogs and cats.

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

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

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 the type of the haircoat it should be considered whether it is necessary to clip the haircoat of the cat prior to treatment.

9. ADVICE ON CORRECT ADMINISTRATION

Wet the animal thoroughly with clean water. Apply Malaseb shampoo to the animal at several points and massage into the coat especially around the lips, under the tail and between the toes. **Make sure that a sufficient amount of the shampoo is used to raise a lather. 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 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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not refrigerate or freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the container: 3 months.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the bottle should be discarded should be worked out.

This discard date should be written in the space provided.

12. SPECIAL WARNINGS

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.

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 etc.)

For external use only.

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

Special precautions for use in animals:

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.

Cats: 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.

User warnings:

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.

Pregnancy:

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. OTHER INFORMATION

For animal treatment only.

Nature and composition of immediate packaging: 250 ml polyethylene bottle with a polypropylene screw cap.

Malaseb shampoo is manufactured under licence from Dermcare Vet, Australia, owner of the trade name Malaseb. EU patent no. 0608308.

UK only: Vm 24883/4005

POM-V

Prescription Only Medicine - Veterinarian

IE only: VPA 10803/005/001

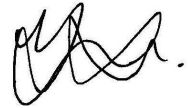
POM

 Prescription Only Medicine

To be supplied only on veterinary prescription.

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

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom.



Approved: 25 July 2019