SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbotis 3mg/ml + 10mg/ml + 1mg/ml ear drops, suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Marbofloxacin……3.0 mg

Clotrimazole…… 10.0 mg

Dexamethasone acetate…… 1.0 mg

(equivalent to Dexamethasone ……..0.9 mg)

Excipient:

Propyl gallate (E310) …… 1.0 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Homogenous beige to yellow oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of otitis externa of bacterial and fungal origin – respectively due to bacteria sensitive to marbofloxacin, and fungi (*Malassezia pachydermatis* sensitive to clotrimazole).

4.3 Contraindications

Do not administer to dogs suffering from perforation of the tympanic membrane.
Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not administer to pregnant or lactating bitches.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Before treating with the veterinary medicinal product, the integrity of the tympanic membrane must be verified.

The external ear canal should be meticulously cleaned and dried before treatment.

Quinolone class drugs have been associated with cartilage erosions in weightbearing joints and other forms of arthropathy in immature animals of various species. The use of the veterinary medicinal product in young animals is not recommended.

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

People with known hypersensitivity to marbofloxacin, dexamethasone, clotrimazole should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin and eyes. In case of accidental contact, wash exposed area thoroughly with water.

Wash hands after use.

In case of accidental ingestion or if skin and eye symptoms persist seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Dogs:

Undetermined frequency (cannot be estimated from the available data)	Elevated serum alkaline phosphatase (ALP) and aminotransferase* Neutrophilia (limited)* Adrenal gland disorder (suppression of function)** Skin thinning** Delayed healing (wounds)**
Rare (1 to 10 animals / 10,000 animals treated):	Deafness***

* Usual adverse reactions associated with corticosteroid drugs such as changes in biochemical and haematological parameters may be observed.

** Prolonged and intensive use of topical corticosteroid preparations is known to trigger local and systemic effects

***Mainly in elderly dogs and mostly of a transient nature

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.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Auricular use.

Shake well before use and squeeze gently to fill the dropper with the veterinary medicinal product.

Apply ten drops into the ear once daily for 7 to 14 days.

After 7 days of treatment, the veterinary surgeon should evaluate the necessity to extend the treatment another week.

One drop of the preparation contains 71µg marbofloxacin, 237µg clotrimazole and 23.7µg dexamethasone acetate.

After application, the base of the ear may be massaged briefly and gently to allow the preparation to penetrate to the lower part of the ear canal.

The external ear canal should be meticulously cleaned and dried before treatment.

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

Changes in biochemical and hæmatological parameters (such as increase of alkaline phosphatase, aminotransferase, some limited neutrophilia, eosinopenia, lymphopenia) are observed with three fold the recommended dosage; such changes are not serious and will reverse once the treatment has stopped.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: dexamethasone and antiinfectives

ATC Vet Code: QS02CA06

5.1 Pharmacodynamic properties

The preparation combines three active ingredients:
- marbofloxacin, a synthetic bactericidal agent belonging to the fluoroquinolone family that acts by inhibiting DNA gyrase. It exhibits a broad spectrum of activity against Gram-positive bacteria (e.g. Staphylococcus intermedius) and against Gram-negative organisms (Pseudomonas aeruginosa, Escherichia coli and Proteus mirabilis).
- clotrimazole, an anti-fungal agent that belongs to the imidazole family and which acts by causing changes in membrane permeability, allowing intracellular

compounds to leak from the cell and thus inhibiting cellular molecular synthesis. It exhibits a wide spectrum of activity and is aimed, in particular, at Malassezia pachydermatis;
- dexamethasone acetate, a synthetic glucocorticoid exhibiting anti-inflammatory and anti-pruritic activity.

5.2 Pharmacokinetic particulars

Pharmacokinetics studies in dogs at the therapeutic dosage have shown that: Marbofloxacin plasma concentrations peak at 0.06 µg/ml on the 14th day of treatment. Marbofloxacin binds weakly to plasma proteins (< 10% in dogs) and is eliminated slowly, mainly in the active form, over 2/3 in urine and over 1/3 in fæces. Clotrimazole absorption is extremely poor (plasma concentration < 0.04 µg/ml). Dexamethasone acetate plasma concentration reaches 1.25 ng/ml on the 14 th day of treatment. Dexamethasone resorption is not increased by the inflammatory process induced by otitis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl gallate (E310)
Sorbitan oleate
Silica, colloidal hydrophobic
Triglycerides, medium-chain

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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: 6 months

6.4 Special precautions for storage

Do not store above 30◦C.

6.5 Nature and composition of immediate packaging

A white LDPE bottle with white LDPE applicator (dropper), closed with white HDPE tamper evident cap.

Package sizes:

Cardboard box with 1 bottle of 15 ml.

Cardboard box with 1 bottle of 25 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32
Lublin 20-616
Poland

8. MARKETING AUTHORISATION NUMBER

Vm 55788/5000

9. DATE OF FIRST AUTHORISATION

20 September 2024

10. DATE OF REVISION OF THE TEXT

September 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

11. 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).

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved: 20 September 2024