ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbotis 3mg/ml + 10mg/ml + 1mg/ml Ear Drops, Suspension for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:
Marbofloxacin……3.0 mg
Clotrimazole…… 10.0 mg
Dexamethasone acetate…… 1.0 mg
(equivalent to Dexamethasone ……..0.9 mg)

3. PACKAGE SIZE

15 ml
25 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Auricular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months by...

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{logo name of the marketing authorisation holder}

14. MARKETING AUTHORISATION NUMBERS

Vm 55788/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Vial 15 ml, 25 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otisan ear drops, suspension (RMS)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Active substances:
Marbofloxacin……3.0 mg
Clotrimazole…… 10.0 mg
Dexamethasone acetate…… 1.0 mg
(equivalent to Dexamethasone ……..0.9 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months by…

{logo name of the marketing authorisation holder}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Otisan 3mg/ml + 10mg/ml + 1mg/ml ear drops, suspension for dogs (RMS)

2. 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)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propyl gallate (E310)	1.0 mg

Homogenous beige to yellow oily suspension.

3. Target species

Dogs

4. Indications for use

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

5. 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.

6. Special warnings

Special precautions for safe use in the target species:
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.

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

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
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.

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

7. Adverse events

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	Deafness***

(1 to 10 animals / 10,000 animals treated):	

* 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Auricular use.
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.

9. Advice on correct administration

Shake well before use and squeeze gently to fill the dropper with the veterinary medicinal product.
The external ear canal should be meticulously cleaned and dried before treatment.
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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 55788/3000

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32, 20-616 Lublin,
Poland
Manufacturer responsible for batch release:
Vet-Agro Multi-Trade Company Sp. z o.o.
Mełgiewska 18, 20-234 Lublin, Poland

Contact details to report suspected adverse reactions:
Vet-Agro Multi-Trade Company Sp. z o.o.
Mełgiewska 18, 20-234 Lublin, Poland
Tel.: +48 81 445 23 00
E-mail: pharmacovigilance@vet-agro.pl

<Local representatives <and contact details to report suspected adverse reactions>:>

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

17 Other information

Gavin Hall

Approved: 20 September 2024