MARBODEX AURAL EAR DROPS, SUSPENSION FOR DOGS

PRODUCT LITERATURE
LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE>
10 ml/20 ml/30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodex Aural Ear Drops, Suspension for Dogs
Marbofloxacin / Clotrimazole / Dexamethasone acetate

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
3.0 mg Marbofloxacin
10.0mg Clotrimazole
0.9mg Dexamethasone (equivalent to 1.0mg dexamethasone acetate)

3. PHARMACEUTICAL FORM

Ear drops, suspension

4. PACKAGE SIZE

10 ml/20 ml/30 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Auricular use.
Shake well for 1 minute before use.
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

Shelf life after first opening the immediate packaging: 3 months
<EXP {month/year}>
Once opened, use by:……

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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 MA HOLDER

(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Station Works, Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4392

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml/20 ml/30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodex Aural Ear Drops, Suspension for Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:
3.0 mg Marbofloxacin
10.0 mg Clotrimazole
0.9 mg Dexamethasone (equivalent to 1.0 mg dexamethasone acetate)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml/20 ml/30 ml

4. ROUTE(S) OF ADMINISTRATION

Auricular use. Shake well before use
Read the package leaflet.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

Once opened use by:
<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
MARBODEX AURAL EAR DROPS, SUSPENSION FOR DOGS

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Station Works, Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

Manufacturer responsible for batch release:
(EU) Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Station Works, Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodex Aural Ear Drops, Suspension for Dogs

Marbofloxacin / Clotrimazole / Dexamethasone acetate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Marbodex Aural Ear Drops suspension for Dogs is a homogenous beige to yellow oily suspension containing 3.0 mg Marbofloxacin, 10.0 mg Clotrimazole, 0.9 mg Dexamethasone (equivalent to 1.0mg dexamethasone acetate) and 1.0 mg Propyl Gallate (E310) per ml.

The product also contains Sorbitan Oleate, Silica Hydrophobic Colloidal and Triglycerides Medium-Chain.

4. INDICATION(S)

Treatment of otitis externa of both bacterial and fungal origin respectively due to bacteria susceptible to marbofloxacin, and fungi especially *Malassezia pachydermatis* susceptible to clotrimazole.

5. CONTRAINDICATIONS

Do not use in dogs suffering from perforation of the tympanic membrane.
Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Usual adverse reactions associated with corticosteroid drugs may be observed (changes in biochemical and haematological parameters, such as increase of alkaline phosphatase, and of aminotransferase, some limited neutrophilia).
Prolonged and intensive use of topical corticosteroid preparations is known to trigger local and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed wound healing.
On rare occasions, the use of this product may be associated with deafness, mainly in elderly dogs and mostly of a transient nature.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1.000 animals treated)
- rare (more than 1 but less than 10 animals in 10.000 animals treated, including isolated reports)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

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

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.

When the product is intended for use in several dogs, use one cannula per dog.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well for 1 minute before use.

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 PERIOD

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 bottle and carton after “EXP”.
Shelf life after first opening the container: 3 months.

When the container is 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 container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antibiotics.

Before treating with the product, the integrity of the tympanic membrane must be verified.
Official and local antimicrobial policies should be taken into account when the product is used.
The external ear canal should be meticulously cleaned and dried before treatment.

Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated.

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

Avoid contact with the eyes in animals. In case of accidental contact, rinse thoroughly with water.

The product should be used based on susceptibility testing of isolated bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands carefully after applying the product.
Avoid contact with eyes. If splashed in the eye, rinse with large amounts of clean water.
If skin or eye symptoms persist, or the product is accidentally swallowed, seek medical attention and show the package insert to the physician.
People with known hypersensitivity (allergy) to (fluoro)quinolones, (cortico)steroids or antifungals and to other ingredients in the product should take care to avoid contact with the product during administration.

Use during pregnancy, lactation:
Do not administer to pregnant or lactating bitches.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
Changes in biochemical and haematological 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.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

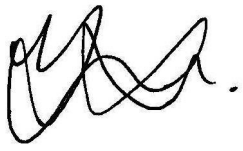
15. OTHER INFORMATION

Packaging Quantities:
Available in vials of 10 ml, 20 ml and 30 ml
Not all pack sizes may be marketed

Marbofloxacin is 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 is 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 is a synthetic glucocorticoid exhibiting anti-inflammatory and anti-pruritic activity.



Approved: 18 August 2020