PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otoxolan ear drops, suspension for dogs
Marbofloxacin/Clotrimazole/Dexamethasone acetate
Marbofloxacinum/Clotrimazolum/Dexamethasoni acetas (for multilingual packaging)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of suspension contains:

Active substances:

Marbofloxacin	3.0 mg
Clotrimazole	10.0 mg
Dexamethasone acetate	1.0 mg
(equivalent to Dexamethasone	0.9 mg)

3. PHARMACEUTICAL FORM

Ear drops, suspension.

4. PACKAGE SIZE

10 ml
20 ml
30 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 3 months
Once opened use by….

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Keep the bottles in the outer carton in order to protect from light.

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 MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4117

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otoxolan ear drops for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3 mg marbofloxacin, 10 mg clotrimazole, 1 mg dexamethasone acetate/ml

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

10 ml
20 ml
30 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:
Otoxolan 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:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer responsible for batch release:
Krka, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otoxolan ear drops, suspension for dogs
Marbofloxacin/Clotrimazole/Dexamethasone acetate

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

Each ml of suspension contains:

Active substances:

Marbofloxacin	3.0 mg
Clotrimazole	10.0 mg
Dexamethasone acetate	1.0 mg
(equivalent to Dexamethasone	0.9 mg)

Excipients:

Propyl gallate (E310)	1.0 mg

Off yellow, opalescent, viscous suspension.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in dogs suffering from perforation of the tympanic membrane.
Do not use in cases of hypersensitivity to the active substances, to other azole antifungal agents or to any other fluoroquinolones or to any of the excipients.
Do not use in animals, where resistance of causative agents to marbofloxacin and/or clotrimazole is known.

See section 12 (Pregnancy and lactation).

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).
On rare occasions, the use of this combination 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)
- 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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs.

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

For auricular use.

Shake well for 30 seconds before use and squeeze gently to fill the dropper with the 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 71 µg marbofloxacin, 237 µg clotrimazole and 23.7 µg dexamethasone acetate.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30 °C.
Keep the bottles in the outer carton in order to protect from light.
Shelf life after first opening the container: 3 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.
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 warnings for each target species:
Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated**.**

Special precautions for use in animals:
Before treating with the product, the integrity of the tympanic membrane must be verified.
Use of the product should be based on susceptibility testing of the bacteria and/or fungi isolated from the animal. If this is not possible, therapy should be based on local (regional) epidemiological information about susceptibility of the target pathogens.
Official and local antimicrobial policies should be taken in to account when the veterinary medicinal product is used.
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.
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.
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.
Avoid contact with eyes in animals. In case of accidental contact, rinse thoroughly with water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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.
Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.
Take care to avoid accidental ingestion. In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.
Wash hands after use.

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

Overdose (symptoms, emergency procedures, antidotes):
Changes in biochemical and haematological parameters (such as increase of alkaline phosphatase, aminotransferase, some limited neutrophilia, eosinopaenia, lymphopaenia) 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

15. OTHER INFORMATION

Box containing 1 x 10 ml and 1 dropper.
Box containing 1 x 20 ml and 2 droppers.
Box containing 1 x 30 ml and 3 droppers.
Not all pack sizes may be marketed.

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

KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
pharmacovigilance.uk@krka.biz

Approved 02 March 2022