ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otoxolan ear drops, suspension

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. PACKAGE SIZE

10 ml
20 ml
30 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Auricular use.
Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.
Once opened use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

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

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

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3081

15. BATCH NUMBER

Lot

INIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otoxolan

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 ml
20 ml
30 ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Otoxolan ear drops, suspension for dogs

2. Composition

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.

3. Target species

Dogs.

4. Indications for use

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 6 (Pregnancy and lactation).

6. Special warnings

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

Special precautions for safe use in the target species:
Before treating with the veterinary medicinal product, the integrity of the tympanic membrane must be verified.
Use of the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product should take care to avoid contact with the veterinary medicinal product during administration.
Avoid contact of the skin and eyes with the veterinary medicinal 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.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Deafness[1]
Undetermined frequency (cannot be estimated from the available data):	Changes in biochemical and haematological parameters (e.g., Elevated serum alkaline phosphatase (ALP), Elevated alanine aminotransferase (ALT)/Elevated aspartate aminotransferase (AST) (elevated liver enzymes), Neutrophilia (increased number of neutrophils))[2]

[1]Mainly in elderly dogs and mostly of a transient nature.
[2]Associated with corticosteroid drugs.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

For auricular use.

Shake well for 30 seconds 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 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 veterinary medicinal product is intended for use in several dogs, use one dropper per dog.

10. Withdrawal periods

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.
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.
Shelf life after first opening the immediate packaging: 3 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 01656/3081

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.

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 and contact details to report suspected adverse reactions:
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

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

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

Gavin Hall
Approved: 18 December 2024