PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomicol ear drops and cutaneous suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of suspension contains:

Miconazole nitrate	23.00 mg (equivalent to 19.98 mg miconazole)
Prednisolone acetate	5.00 mg
Polymyxin B sulfate	5500 IU (equivalent to 0.5293 mg polymyxin B sulfate)

3. PACKAGE SIZE

15 ml

4. TARGET SPECIES

dogs, cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For auricular and cutaneous use.
Shake well before use (10 seconds).

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C. Store in the original container 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

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/5072

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Always wear single use disposable gloves when applying the product to animals.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM – V
Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON BLISTER OR STRIPS
{Label}

1.NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomicol

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

15 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

KRKA

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomicol ear drops and cutaneous suspension for dogs and cats

2. COMPOSITION

Each ml of suspension contains:

Active substances:

Miconazole nitrate	23.00 mg (equivalent to 19.98 mg miconazole)
Prednisolone acetate	5.00 mg
Polymyxin B sulfate	5500 IU (equivalent to 0.5293 mg polymyxin B sulfate)

White suspension.

3. TARGET SPECIES

Dogs and cats.

4. INDICATIONS FOR USE

For the treatment of primary and secondary infections of skin (eczema, dermatitis, pyoderma) and skin adnexa (hair, claws, sweat glands), as well as for the treatment of otitis externa, caused by infections with the following miconazole and polymyxin B sensitive pathogens:

Gram-positive bacteria
Staphylococcus spp.
Streptococcus spp.

Gram-negative bacteria
Pseudomonas spp.
Escherichia coli

Yeasts and fungi
Malassezia pachydermatis
Candida spp.
Microsporum spp.
Trichophyton spp.

For the topical treatment of otitis externa caused by the ear mite *Otodectes cynotis*.

5. CONTRAINDICATIONS

Do not use in animals with perforated ear drums since Polymyxin B is known to be a potential ototoxic agent.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. SPECIAL WARNINGS

Special warnings:
As the product is a prescription only medicine, treatment should be closely supervised by a veterinary practitioner.

Special precautions for use in animals:
For external use only.
Due to the likely variability (temporal, geographical) in the emergence of bacterial resistance to polymyxin B, bacteriological sampling and sensitivity testing (antibiogram) is recommended. If there is overgrowth of resistance bacteria and/or fungi, treatment with this product should be discontinued and treatment with an appropriate alternative should be initiated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to prednisolone, polymyxin B or miconazole should avoid contact with the veterinary medicinal product.
The veterinary medicinal product may cause irritation to skin and eyes. Avoid contact with skin or eyes. Personal protective equipment consisting of single use disposable gloves should be worn when applying the veterinary medicinal product to animals. In case of accidental spillage, skin or eyes should be rinsed immediately with plenty of water.
Take care to avoid accidental ingestion, especially by a child. In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Corticosteroids are not recommended for use in pregnant animals.

Interaction with other medicinal products and other forms of interaction:
Do not use concomitantly with medicines that induce ototoxicity.

Overdose:
In case of overdose, no other adverse events are known other than those mentioned in section “Adverse events”. In case of accidental ingestion by licking, no toxic effects were observed.

7. ADVERSE EVENTS

Dog, cat:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Deafness[1]
Undetermined frequency (cannot be estimated from the available data):	Local immune deficiency[2,3] Skin thinning[2] Delayed healing[2] Teleangiectasia[2] Increased vulnerability of the skin (with bleeding)[2]

[1]In animals treated for otitis externa, especially in older dogs. Treatment should be discontinued.
[2]With prolonged use due to the contained glucocorticoid.
[3]Associated with increased susceptibility to infection.

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 using the contact details at the end of this leaflet, or via your national reporting system {https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine}.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

This product is for topical administration.

At the beginning of treatment, hair surrounding or covering the lesions must be clipped; this should be repeated during treatment if necessary.

Ears: Clean the auditory canal and place a few drops of the product into the ear twice daily. For infections caused by *Otodectes cynotis*, instill five drops twice daily for 14 days.
Massage the ear and the auditory canal gently but thoroughly to ensure proper distribution.

Skin: Having ensured the area to be treated is clean, apply a few drops of the product (depending on lesion size) twice a day and rub well.

Treatment should be continued until a few days after complete disappearance of the clinical symptoms. In some obstinate cases, treatment may be required for 2 to 3 weeks (see also »Adverse events«).

Where ear mite infestation is present, consideration should be given to treating both ears even if infestation is only apparent in one ear.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the bottle vigorously and ensure the product is fully resuspended before use.

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C. Store in the original container in order to protect from light.

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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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 01656/5072

Folding box consist of:
- white bottle 15 ml, made of low density polyethylene (LDPE)
- white dropper, made of low density polyethylene (LDPE)
- white screw closure with tamper proof ring, made of high density polyethylene (HDPE)

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 manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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.

17. OTHER INFORMATION

POM – V
Veterinary medicinal product subject to prescription.

For animal treatment only.

Gavin Hall

Approved: 12 June 2024