PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neptra ear drops solution

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (1 ml): 16.7 mg terbinafine hydrochloride, 16.7 mg florfenicol, 2.2 mg mometasone furoate

3. PACKAGE SIZE

1 tube
2 tubes
10 tubes
20 tubes

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Auricular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °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

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

Vm 04895/5007

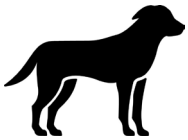
15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neptra



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

16.7 mg terbinafine hydrochloride, 16.7 mg florfenicol, 2.2 mg mometasone furoate

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Single-dose container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neptra

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Neptra ear drops solution for dogs

2. Composition

1 dose (1 ml) contains:

Active substances:

Florfenicol: 16.7 mg
Terbinafine hydrochloride: 16.7 mg, equivalent to
terbinafine base: 14.9 mg Mometasone furoate: 2.2 mg

Clear, colourless to yellow, slightly viscous liquid.

3. Target species

Dogs

4. Indications for use

For the treatment of acute canine otitis externa or acute exacerbations of recurrent otitis caused by mixed infections of *Staphylococcus pseudintermedius* and *Malassezia pachydermatis*.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances, to other corticosteroids or to any of the excipients.

Do not use if the ear drum is perforated.
Do not use in dogs with generalised demodicosis.
Do not use in pregnant or breeding animals.

6. Special warnings

Special warnings:

Bacterial and fungal otitis is often secondary to other conditions. In animals with a history of recurrent otitis externa, the underlying causes of the condition such as allergy or anatomical conformation of the ear must be addressed in order to avoid ineffective treatment with a veterinary medicinal product.

In cases of parasitic otitis, an appropriate acaricidal treatment should be implemented.

Ears must be cleaned before administration of the product. It is recommended not to repeat ear cleaning until 28 days after administration of the product.

In clinical trials, only saline was used for ear cleaning before treatment initiation with the veterinary medicinal product.

This combination is intended for the treatment of acute otitis when mixed infections caused by *Staphylococcus pseudintermedius* susceptible to florfenicol and *Malassezia pachydermatis* susceptible to terbinafine have been demonstrated.

Special precautions for safe use in the target species:

The safety of the veterinary medicinal product has not been established in dogs less than 3 months of age. Target animal safety was not studied in dogs under 4 kg bodyweight. However, no safety issues were identified in field studies in dogs weighing less than 4 kg.

Before the veterinary medicinal product is applied, the external auditory canal must be examined thoroughly to ensure that the ear drum is not perforated. Re-evaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.

After the administration, wet ears or clear discharge can be observed which is not related to the disease pathology.

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 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.

Use of the veterinary medicinal product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to florfenicol and fungi resistant to terbinafine and may decrease the effectiveness of treatment with other antibiotics and antifungal agents.

Decreased cortisol levels were observed after product instillation in tolerance studies (before and after ACTH stimulation), indicating that mometasone furoate is absorbed and enters the systemic circulation. The main findings observed at the 1X dose were decreases in cortical response to ACTH stimulation, decreased absolute lymphocyte and eosinophil counts, and decreased adrenal weight.
Prolonged and intensive use of topical corticosteroid preparations is known to trigger systemic effects, including suppression of adrenal function (see section ‘Overdose’).

If hypersensitivity to any of the components occurs, the ear should be thoroughly washed. Additional corticosteroid treatments should be avoided.

Use with caution in dogs with a suspected or confirmed endocrine disorder (e.g., diabetes mellitus, hypo- or hyperthyroidism, etc.).

Caution should be taken to prevent the veterinary medicinal product from getting into the eyes of the dog being treated e.g. by restraining the dog's head to prevent shaking (see section Advice on correct administration'). In case of exposure to the eye, rinse with plenty of water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product has serious eye irritation potential. Accidental eye exposure may occur when the dog shakes its head during or just after administration. To avoid this risk for the owners, it is recommended that this veterinary product is administered only by veterinarians or under their close supervision. Appropriate measures (e.g. wearing safety glasses during administration, massaging the ear canal well after administration to ensure even distribution of product, restraining the dog after administration) are needed to avoid exposure to the eyes. In case of accidental ocular exposure, flush the eyes thoroughly with water for 10 to 15 minutes. If symptoms develop, seek medical advice and show the package leaflet or the label to the physician.

Although no potential for skin irritation was indicated by experimental studies, contact of the product with the skin should be avoided. In case of accidental skin contact, wash exposed skin thoroughly with water.
May be harmful after ingestion. Avoid ingestion of the product including hand-to-mouth exposure. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

The safety and efficacy of the veterinary medicinal product in cats has not been evaluated. Post- marketing surveillance shows that the use of the product in cats can be associated with neurological signs (including ataxia, Horner's syndrome with protrusion of membrane nictitans, miosis, anisocoria), internal ear disorders (head tilt) and systemic signs (anorexia and lethargy). The use of the veterinary medicinal product in cats should therefore be avoided.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

Fertility:
Studies to determine the effect on fertility in dogs have not been conducted. Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction: None known.
Compatibility with ear cleaners, other than saline solution, has not been demonstrated.

Overdose:
Auricular administration of up to five times the recommended dose at biweekly intervals for a total of three treatments was generally well tolerated. The most prominent effects were consistent with glucocorticoid administration; specific observations included suppression of the adrenal cortical response to ACTH-stimulation, decreased adrenal weight and atrophy of the adrenal cortex, decreased absolute lymphocyte and eosinophil counts, increased absolute neutrophil count, increased liver weight with hepatocellular enlargement/cytoplasmic change, and decreased thymus weight. Other potentially treatment-related effects included mild changes to aspartate aminotransferase (AST), total protein, cholesterol, inorganic phosphorus, creatinine and calcium. After 3 weekly administrations of up to 5x the recommended posology, the test product induced slight erythema in one or both ears that returned to normal within 48 hours.

Special restrictions for use and special conditions for use:
Administration by a veterinarian or under their close supervision.

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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site erythema, Application site inflammation, Application site pain[1] Hyperactivity, Vocalisation[1] Emesis Deafness[2], Impaired hearing[2], Internal ear disorder, Head shake[1] Eye disorder (e.g. blepharospasm, conjunctivitis, corneal ulcer, eye irritation, keratoconjunctivitis sicca) Ataxia, Nystagmus Anorexia

[1]Observed to occur shortly after product administration.[2]Mainly in elderly animals

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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

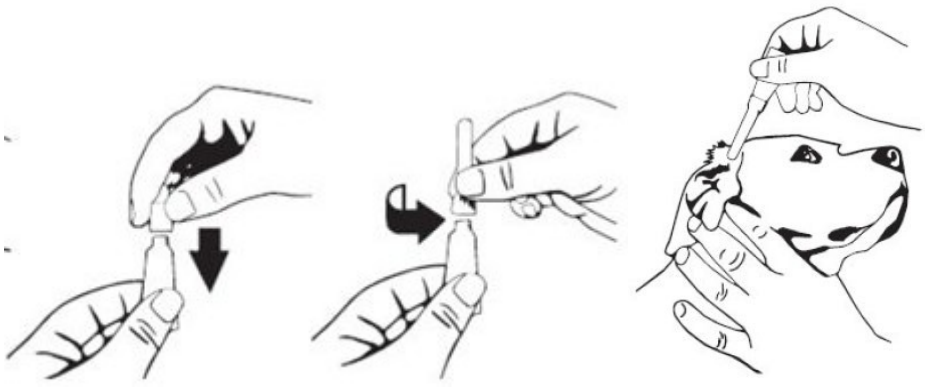
Auricular use.

Single treatment.

The recommended dosage is 1 single-dose container (i.e. 1 ml of solution) per infected ear. The maximum clinical response may not be seen until 28 days after administration.
Shake well before use for 5 seconds.
While holding the single-use container in an upright position, remove the cap.
Use the upper end of the cap to completely break the seal and then remove cap from the single-use container.
Screw the applicator nozzle onto the single-use container.
Insert the applicator nozzle into the affected external ear canal and squeeze the entire contents into the ear.

For monolingual packaging only:
<Examples are illustrated below.>

For multilingual packaging only:
<Examples are illustrated at the end of the leaflet.>



9. Advice on correct administration

Clean with saline solution and dry the external ear canal before administering the product. After application, gently massage the base of the ear for 30 seconds to allow distribution of the solution. Restrain the dog's head to prevent shaking, for 2 minutes.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

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

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 04895/5007

Single-use sealed laminated tube containing 1 ml solution, with polypropylene cap and separate LDPE applicator nozzle packed in a transparent plastic blister.
Carton containing 1, 2, 10 or 20 blisters.

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:

Elanco Animal Health GmbH
Alfred-Nobel-Str. 50
40789 Monheim
Germany

Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH Projensdorfer Str. 324, 24106 Kiel Germany

17. Other information

POM-V

Gavin Hall
Approved: 19 January 2025