

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DUOMYXIN, 3 400 IU/ml / 10 000 IU/ml, Eye drops, powder and solvent for solution for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyophilisate

One vial of 2 g contains:

Active substances:

Neomycin (as sulfate)17,000 IU
Polymyxin B (as sulfate)50,000 IU

Excipient:

Qualitative composition of excipients and other constituents
Disodium edetate
Dextran 70 for injection
Water for injections

White to cream powder.

Solvent

One 5-mL bottle contains:

Excipient:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzalkonium chloride	0.50 mg
Dextran 70 for injection	
Sodium dihydrogen phosphate dihydrate	
Disodium phosphate dodecahydrate	
Sodium chloride	
Water for injections	

Practically limpid, colourless and practically particles-free solution.

Reconstituted solution

1 mL contains:

Active substances:

Neomycin (as sulfate)3,400 IU
Polymyxin B (as sulfate)10,000 IU

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Lyophilisate:	
Disodium edetate	
Dextran 70 for injection	
Water for injections	
Solvent:	
Benzalkonium chloride	0.10 mg
Dextran 70 for injection	
Sodium dihydrogen phosphate dihydrate	
Disodium phosphate dodecahydrate	
Sodium chloride	
Water for injections	

Practically limpid, colourless to pale yellow, practically particles-free solution.

3. CLINICAL INFORMATION**3.1 Target species**

Dogs and cats.

3.2 Indications for use for each target species

Treatment of superficial eye infections caused by bacteria susceptible to polymyxin B and neomycin based on susceptibility testing.

3.3 Contraindications

Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for useSpecial precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to neomycin and may decrease the effectiveness of treatment with other aminoglycosides due to the potential for cross-resistance.

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. This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.

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

The veterinary medicinal product may cause hypersensitivity reactions following ingestion or skin contact due to the presence of neomycin, polymyxin B and benzalkonium chloride. People with known hypersensitivity to any of the components should avoid contact with the veterinary medicinal product. In case of accidental spillage onto skin rinse immediately with plenty of water. If you develop symptoms such as a skin rash following exposure, seek medical advice and show the package leaflet to the physician.

The veterinary medicinal product may cause irritation. Avoid contact with eyes. In case of accidental spillage into eyes, rinse immediately with plenty of water.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

In dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Eye irritation and eye pain*
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*These signs have been observed upon instillation of the eye drops.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment of the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Ocular use.

The veterinary medicinal product is to be administered into the affected eye, at a dose of 2 drops, 3 to 4 times daily. Both eyes may be treated with the same dose at the same time, if necessary.

Duration of treatment: 8 to 10 days.

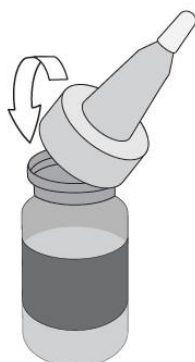
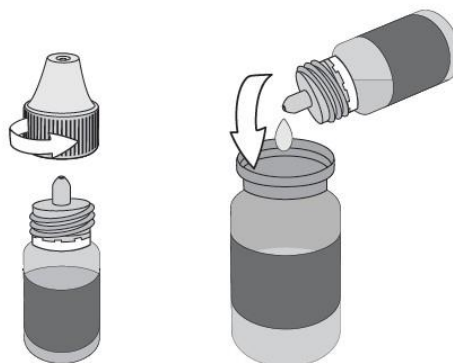
Instructions for use

Clean hands carefully before handling and reconstituting the eyedrops solution in order to avoid microbiological contamination of the veterinary medicinal product. It is recommended that the reconstitution of the eyedrops is done by a veterinarian or a pharmacist.



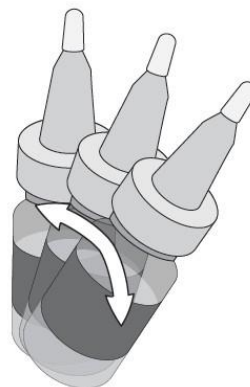
Open the amber glass container by removing the aluminium cap and then the stopper.

Remove the screw cap of the solvent and add the solvent to the freeze dried powder in the amber glass container by gently squeezing the bottle. Make sure that all solvent is added.



Press the dropper (with cap) onto the vial.

The powder dissolves almost immediately, shaking gently helps to have an immediate homogeneous solution.



Remove the cap from the dropper to administer the veterinary medicinal product.

Keep the dog's/cat's head steady in a slightly upright position. Hold the container in an upright position without touching the eye. Rest your hand/little finger on the forehead of the dog/cat to maintain distance between the container and the eye. Pull the eyelid of the affected eye downwards, this will form a little eyelid pouch. Gently squeeze the dropper to administer two drops into the eyelid pouch that you created.

Be careful not to touch the dropper tip after opening the container and replace the cap after use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS01AA30

4.2 Pharmacodynamics

Neomycin is an antibiotic of the aminoglycoside family. It is a bactericidal antibiotic with a broad spectrum of action, covering most of Gram-positive and Gram-negative bacteria. It acts after diffusion in the bacterial cytoplasm, by binding to the ribosomes, thus inhibiting bacterial protein synthesis.

Resistance to neomycin occurs by four different mechanisms including (1) enzymatic inactivation, (2) alterations of the ribosomal subunit within the bacterial cell; (3) reduced permeability to the antibiotic, and (4) efflux pumps. The most common resistance mechanism is the production of aminoglycoside-modifying enzymes. Genetic information may be carried on the bacterial chromosome or on plasmids. Co-resistance within the aminoglycosides group, as well as cross-resistance with other antibiotic groups may occur.

Polymyxin B belongs to the family of polypeptide antibiotics. It is a bactericide mainly active on Gram-negative bacilli (*Proteus*, Enterobacteriaceae, *Pseudomonas* infections). It acts by binding to the phospholipid membrane, breaking the cytoplasmic membrane of the bacteria.

Bacterial resistance to polymyxins is mostly associated with modifications of the LPS. It may be supported chromosomally or encoded on transposable genetic elements, namely *mcr* genes.

4.3 Pharmacokinetics

In corneal diseases, neomycin and polymyxin B can penetrate the eye tissue after local application. If the cornea is intact, the effect is essentially limited to the surface tissue. Data on systemic absorption are not available.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

Shelf life after reconstitution according to directions: 10 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Amber glass vial type I (lyophilisate)

Chlorobutyl stopper (lyophilisate)

Tear-off aluminium capsule (lyophilisate)

Low density polyethylene bottle (solvent)

Low density polyethylene dropper (solvent)

High density polyethylene screw cap (solvent)

PVC dropper with low density polyethylene cap (reconstituted solution)

Box of 1 vial of lyophilisate, 1 bottle of 5 mL solvent and 1 dropper.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Domes Pharma

7. MARKETING AUTHORISATION NUMBER(S)

VPA23340/007/001

8. DATE OF FIRST AUTHORISATION

09/12/2022

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

23/11/2022

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).