LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Reconstituted solution
Each 1 mL contains:

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

3. PACKAGE SIZE

5 mL

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Ocular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}

Once reconstituted use within 10 days.

9. SPECIAL STORAGE PRECAUTIONS

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

DOMES PHARMA

14. MARKETING AUTHORISATION NUMBERS

AT: Zul.Nr.: 841593
BE: BE-V661546
DE: V7008094.00.00
DK: 67168
EL: 17836/15-02-2024
ES: 4148 ESP
FI: 40405
IE: VPA23340/007/001
IT: AIC 105676011
LU: V 355/22/11/0005
NL: REG NL 129383
NO: MTnr. 21-14505
PL: 3300/24
PT: 1554/01/23DFVPT
RO: 230174
SE: 65175

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Solvent - label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DUOMYXIN
Solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mL

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Lyophilisate / Reconstituted solution - label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DUOMYXIN

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3,400 IU/mL / 10,000 IU/mL

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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. Composition

Lyophilisate
Each vial of 2 g contains:

Active substances:
Neomycin (as sulfate) .....17,000 IU
Polymyxin B (as sulfate) .....50,000 IU

White to cream powder.

Solvent
Each 5-mL bottle contains:

Excipients:

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

Practically limpid, colourless and practically particles-free solution.

Reconstituted solution
Each 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**
Benzalkonium chloride	0.10 mg

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

3. Target species

Dogs and cats.

4. Indications for use

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

5. Contraindications

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

6. Special warnings

Special 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 be cause irritation. Avoid contact with eyes. In case of accidental spillage into eyes, rinse immediately with plenty of water.
Wash hands after use.

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

7. Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Eye irritation and eye pain*

*These signs have been observed upon instillation of the eye drops.

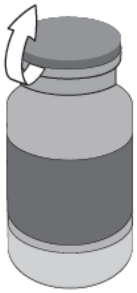
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that medicine has not worked, please contact, in the first instance your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

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

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.

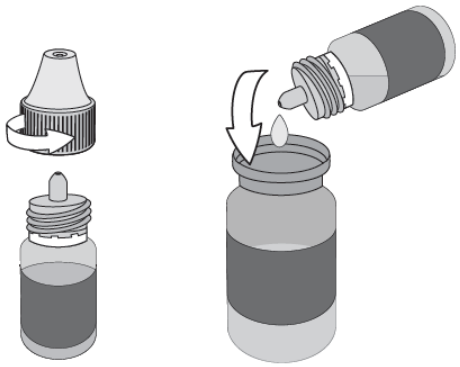
9. Advice on correct administration

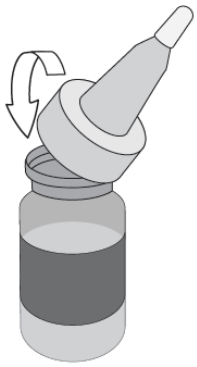
Clean hands carefully before handling and reconstituting the eyedrops solution in order to avoid microbiological contamination of the veterinary medicinal product. It is recommended that the reconstitution of the eyedrops is done by a veterinarian or a pharmacist.



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

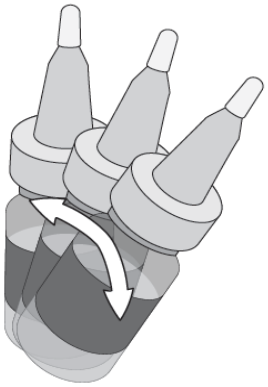
Remove the screw cap of the solvent and add the solvent to the freeze dried powder in the amber glass container by gently squeezing the bottle. Make sure that all solvent is added.





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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

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

Shelf life after reconstitution according to directions: 10 days.

12. Special precautions for disposal

Medicine 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

Marketing authorisation numbers:
AT: Zul.Nr.: 841593
BE: BE-V661546
DE: V7008094.00.00
DK: 67168
EL: 17836/15-02-2024
ES: 4148 ESP
FI: 40405
IE: VPA23340/007/001
IT: AIC 105676011
LU: V 355/22/11/0005
NL: REG NL 129383
NO: MTnr. 21-14505
PL: 3300/24
PT: 1554/01/23DFVPT
RO: 230174
SE: 65175

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

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse events>:
DOMES PHARMA
3 Rue André Citroën
63430 PONT-DU-CHATEAU
France

Manufacturer responsible for batch release:
TUBILUX PHARMA
VIA COSTARICA, 20/22
00071 POMEZIA (RM)
ITALY

<Local representatives <and contact details to report suspected adverse events>:>

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

17. Other information