ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton
5 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stromease 25 mg/ml eye drops, solution for dogs and cats
Acetylcysteine

2. STATEMENT OF ACTIVE SUBSTANCES

Acetylcysteine 25.00 mg/ml

3. PHARMACEUTICAL FORM

Eye drops, solution

4. PACKAGE SIZE

5 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

7.METHOD AND ROUTE(S) OF ADMINISTRATION

Ocular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the vial: 7 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA
3 Rue André Citroën
63430 Pont-du-Château
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 54982/5008

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stromease 25 mg/ml eye drops, solution
Acetylcysteinum

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Stromease 25 mg/ml eye drops, solution for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
DOMES PHARMA
3 Rue André Citroën
63430 Pont-du-Château
FRANCE

Manufacturer responsible for batch release:
PHARMASTER+
Z.I. de Krafft
67150 ERSTEIN
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stromease 25 mg/ml eye drops, solution for dogs and cats
acetylcysteine

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Acetylcysteine	25.00 mg

Excipients:

Benzalkonium chloride	0.10 mg
Dithiothreitol	4.00 mg
Disodium edetate	0.50 mg

Clear, colourless solution.

4. INDICATION(S)

Supportive treatment of corneal ulcers.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

As with any eye drops solution, mild and short discomfort reactions may occur upon administration.
Irritation or inflammation of the eye and/or its adnexa have been reported in very rare cases following use of the medicinal product.
In very rare cases, blinking of the eyelids or even transient closure of the eye, eye redness or conjunctival oedema have been reported, particularly in dogs, according to pharmacovigilance data.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Ocular use.

The product is to be administered into the affected eye(s), at a dose of 2 eye drops, 3 to 4 times daily.

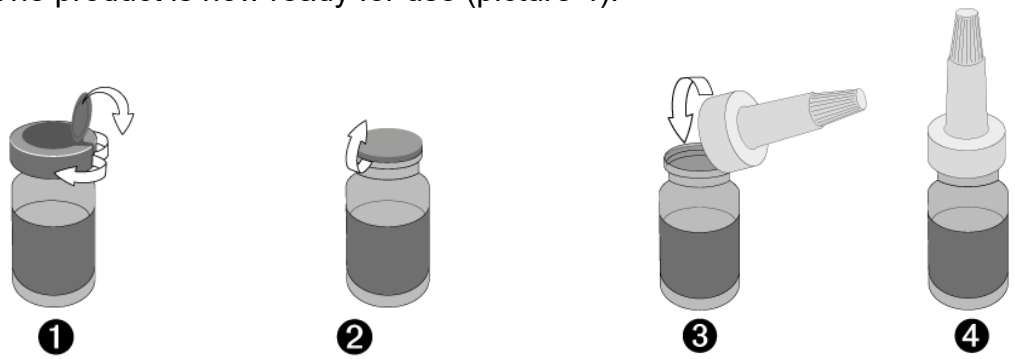
Treatment should be continued in accordance with the instructions given by the individual veterinarian.

9. ADVICE ON CORRECT ADMINISTRATION

<u>Instructions for opening the container and attachment of dropper applicator:</u>

- Wash hands carefully in order to avoid microbiological contamination of the content in the vial.
- Flip open the metal cap and pull it all the way down along the pre-cut lines. Then remove the rest of the metal seal (picture 1).
- Remove the orange colored stopper (picture 2) from the vial.
- Do not touch the opening of the vial after removing the stopper.
- Take the dropper with the small white screw cap on the top out of its sachet, without touching the end intended to be attached to the vial, attach it (picture 3) to the vial and do not remove it anymore.

- The product is now ready for use (picture 4).



Instructions for use
Remove the small white screw cap to administer the product. Keep the dogs/cats 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. Gently 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 white cap after use. Place the container back into the carton in the upright position and store out of sight and reach of children until the next medication.

When treatment is combined with other ocular products, leave at least 5 to 10 minutes between treatments. If treatment is combined with non-aqueous oily eye products, administer acetylcysteine eyedrops first.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the vial: 7 days.

12. SPECIAL WARNING(S)

Special warnings for each target species
None.

Special precautions for use in animals
Ocular re-examination should be made at frequent intervals during therapy.
For the correct treatment of corneal ulceration, the underlying cause and/or the complicating factors should be identified and properly treated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.

Pregnancy and lactation:
Studies in rats and rabbits did not show toxicity in the pregnant female. The safety of the veterinary medicinal product has not been established during pregnancy and lactation in bitches or queens. Use only in accordance with the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interactions
None known.

Overdose (symptoms, emergency procedures, antidotes):
None known.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment

BLUE BOX Requirement UK (NI)

Dispose of waste material in accordance with local requirements. *Medicines should not be disposed of via wastewater.* *Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.'*

14. 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.

15. OTHER INFORMATION

Amber glass bottle type I containing 5 ml, with bromobutyl stopper type I and tear-off aluminium cap.
White PVC dropper with white HDPE cap.
Each vial is packed into a cardboard box.

Gavin Hall

Approved 07 October 2024