

**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. SPECIFIC 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 Andre Citroën  
63430 Pont-Du-Chateau  
France

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 54982/4000

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**5 ml 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 Andre Citroën  
63430 Pont-Du-Chateau  
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
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**Excipients:**

Benzalkonium chloride	0.10 mg
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Dithiothreitol	4.00 mg
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Disodium edetate	0.50 mg
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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. 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.

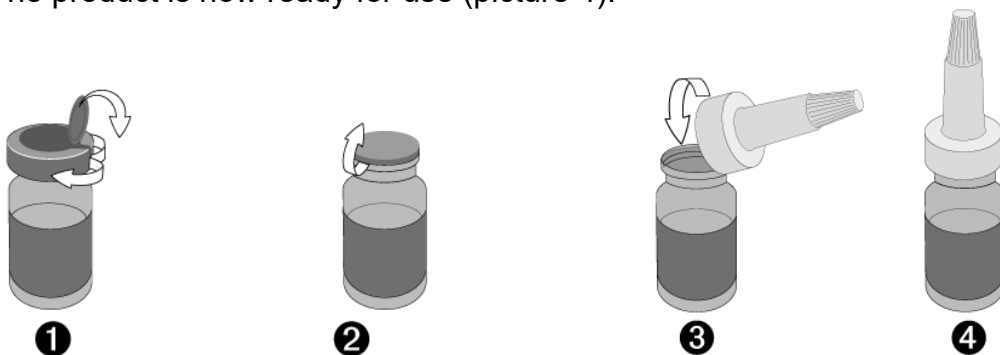
The product is to be administered into the affected eye(s), at a dose of 2 eye drops, 3 to 4 times daily.

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

## 9. ADVICE ON CORRECT ADMINISTRATION

### Instructions for opening the container and attachment of dropper applicator:

- 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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

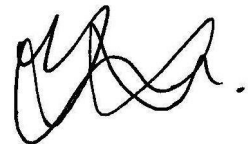
Xxxxxx

**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.



Approved: 26 October 2021