1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Acetylcysteine 25.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Dithiothreitol	4.00 mg
Disodium edetate	0.50 mg
Benzalkonium chloride	0.10 mg
Dextran 70	
Sodium dihydrogen phosphate dihydrate	
Disodium phosphate	
Sodium hydroxide (for pH adjustment)	
Purified water	

Colourless, practically clear solution, practically free of particles.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each target species

Supportive treatment of corneal ulcers.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction[1] Eye irritation[2], Eye inflammation[2] (blinking, closed eyelid, eye redness, conjunctival oedema)[3]

[1] mild and short, referring to discomfort in the eye occurring after the application of eye drops
[2] and/or its adnexa
[3] particularly in dogs.

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 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.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of toxic effects in the pregnant female.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

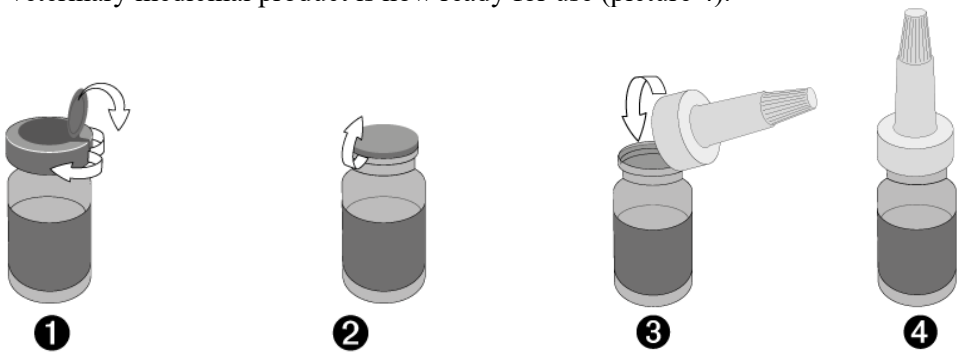
3.9 Administration routes and dosage

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

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 veterinary medicinal product is now ready for use (picture 4).



Instructions for use:
Remove the small white screw cap to administer the veterinary medicinal 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.

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

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: QS01XA08

4.2 Pharmacodynamics

Acetylcysteine is a mucolytic and proteolytic agent. N-acetylcysteine is a derivative of the amino acid l-cysteine and inhibits collagenase irreversibly by reducing disulphide bonds and chelating calcium and zinc. It also inhibits matrix metalloproteinase-9 (MMP-9) production by corneal epithelial cells. Although MMPs play a role in initial corneal wound healing, down-regulation is necessary to prevent corneal digestion and allow corneal wound healing.
The excipient dextran ensures good diffusion and prolonged contact time of the active ingredients.

4.3 Pharmacokinetics

One study demonstrated, following application of radiolabelled cysteine, that acetylcysteine diffuses at the level of the cornea and the aqueous humor, resulting in intraocular penetration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 7 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 bottle type I containing 5 ml, with bromobutyl or chlorobutyl rubber stopper type I and tear-off aluminium cap.
White PVC dropper with white HDPE cap.
Cardboard box of 5 ml vial with dropper

5.5 Special precautions for the disposal of unused veterinary medicinal products 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)

VPA23340/002/001

8. DATE OF FIRST AUTHORISATION

17/06/2022

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

30/07/2025

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).