SUMMARY OF PRODUCT CHARACTERISTICS

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:

Benzalkonium chloride	0.10 mg
Dithiothreitol	4.00 mg
Disodium edetate	0.50 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution
Clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

Supportive treatment of corneal ulcers.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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, especially blinking of the eyelids or even closure of the eye, eye redness or conjunctival oedema, 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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

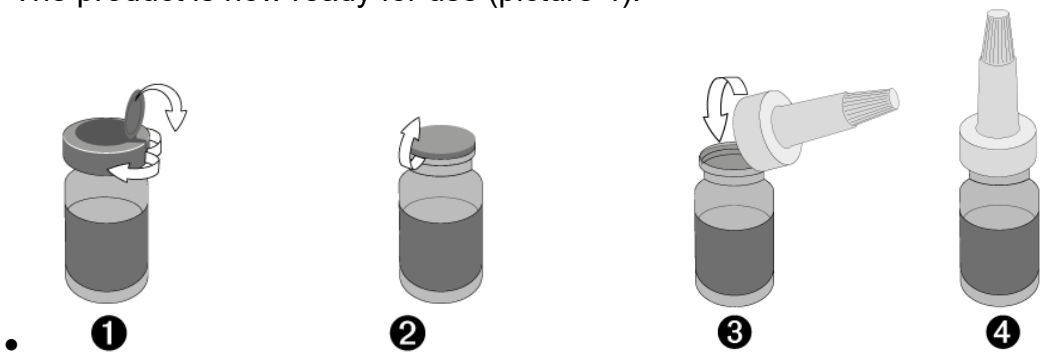
4.9 Amounts to be administered and administration route

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.

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not known.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ophthalmologicals, acetylcysteine
ATC vet code: QS01XA08

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Benzalkonium chloride
Dithiothreitol
Dextran 70
Sodium dihydrogen phosphate dihydrate
Disodium phosphate
Sodium hydroxide (for pH adjustment)
Purified water

6.2 Major incompatibilities

Not applicable.

6.3 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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Domes Pharma
3 Rue André Citroën
63430 Pont-du-Château
France

8. MARKETING AUTHORISATION NUMBER

Vm 54982/5008

9. DATE OF FIRST AUTHORISATION

26 October 2021

10. DATE OF REVISION OF THE TEXT

February 2025

Gavin Hall
Approved: 23 April 2025