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TVM UK Animal Health Ltd (trading as Dômes Pharma)

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Email:help@domespharma.com

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

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Anti-collagenase

Active ingredient: Acetylcysteine

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

Product index: Stromease 25mg/ml eye drops

Incorporating:

Presentation

Each ml contains Acetylcysteine 25mg/ml

Eye drops, clear colourless solution

Uses

Supportive treatment of corneal ulcers in dogs and cats.

Dosage and 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.

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.

• Remove the orange coloured stopper 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 to the vial and do not remove it anymore.

• The product is now ready for use.

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.

Contra-indications, warnings, etc

Contraindications

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

Special warnings for each target species

None.

Adverse reactions (frequency and seriousness)

As with any eye drops solution, mild and short discomfort reactions may occur upon administration

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 complication 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

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.

Interaction with other medicinal products and other forms of interaction

None known,

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

Not known.

Pharmaceutical precautions

Store out of the sight and reach of children.

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

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 7 days

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

Legal category

Legal category:POM-V

Packaging quantities

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.

Marketing Authorisation Holder (if different from distributor)

Domes Pharma

3 Rue Andre Citroën

63430 Pont-Du-Chateau

France

Further information

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.

Pharmacokinetic properties

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.

Marketing Authorisation Number

Vm 54982/4000

Significant changes

GTIN

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