

[Version 8.1,01/2017]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intubeaze 20 mg/ml laryngopharyngeal spray, solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Lidocaine hydrochloride monohydrate 20 mg
(equivalent to lidocaine 16.2 mg)

Each actuation (0.14 ml) contains 2.8 mg of lidocaine hydrochloride monohydrate, which corresponds to 2.27 mg of lidocaine.

Excipients:

Chlorocresol 1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Laryngopharyngeal spray, solution.
Clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

Local anaesthesia of the laryngeal mucosa of the cat in order to facilitate endotracheal intubation by preventing the stimulation of the laryngeal reflex.

4.3 Contraindications

Do not use in animals which are hypovolaemic or show heart block. Do not use in known cases of hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings for each target species

Laryngeal spasm can also be stimulated by removal of the endotracheal tube. This should be carried out while the patient is still under anaesthesia.

4.5 Special precautions for use

Special precautions for use in animals

Use with care in cases with hepatic and or cardiac insufficiency.
It is advisable to cold sterilise the nozzle between uses to avoid the spread of infection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- Lidocaine and chlorocresol may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to these substances should avoid contact with the product.
- Accidental exposure to this product may lead to local effects such as numbing, and systemic effects, such as dizziness or drowsiness. Accidental exposure, particularly oral, eye and inhalation exposure, should be avoided.
- Wear gloves when handling the product and wash any exposed areas after use. If accidental exposure to eyes occurs, rinse with water.
- In cases of severe or extended reactions, seek medical advice and show the label to the physician.
- Lidocaine can form genotoxic and mutagenic metabolites in humans. These metabolites can also induce, in long-term toxicology studies in rats, carcinogenic effects at high doses.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy or lactation

Laboratory studies in mice have shown evidence of foetotoxic effects at high doses. No safety studies have been conducted with the product in pregnant queens. Use only according to 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

For laryngopharyngeal use.

Give one or two sprays at the back of the throat.

Prior to use, prime the pump until liquid is released. Minimum of 4 sprays are recommended for priming the bottle before first use and at least 2 sprays are recommended for re-priming if unused for 7 days or longer.

Each spray (approximately 0.14 ml) contains approximately 2.8 mg of lidocaine hydrochloride monohydrate, which corresponds to 2.27 mg of lidocaine.

Allow 30-90 seconds before attempting intubation, so that the larynx is relaxed.

It should be noted that when removing the actuator from the spray pump it should be done vertically and not at an angle to ensure the pin does not get damaged.

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

Maintain a patent airway and support ventilation with oxygen.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Throat preparations, local anaesthetic, lidocaine
ATC vet code: QR02AD02

5.1 Pharmacodynamic properties

Lidocaine acts by preventing the generation and conduction of nerve impulses. It prevents the increase in permeability of excitable membranes to sodium ions. Small, non-myelinated nerve fibres are more susceptible than are large fibres and the sensation of pain is the first modality to be lost. The product has a duration of action of approximately 15 minutes.

5.2 Pharmacokinetic particulars

Lidocaine is metabolised mainly in the liver and excreted via the kidneys. Approximately 95% is excreted via the form of various metabolites while 5% is excreted unchanged.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Chlorocresol
Water for injections

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening: 3 months

6.4. Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

A clear, colourless Type I glass vial with a polypropylene and polyethylene spray pump and actuator containing 10 ml. Vials are packaged in 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

Dechra Limited
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8. MARKETING AUTHORISATION NUMBER

Vm 10434/4093

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 November 2018

10. DATE OF REVISION OF THE TEXT

November 2018