SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intubeaze 20 mg/ml oromucosal spray for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Lidocaine hydrochloride 20 mg

(Lignocaine hydrochloride)

Excipients:

Sodium chloride 5 mg Chlorocresol 1 mg

Water for injections

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oromucosal spray.

Clear, colourless mobile 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 exceed recommended dose.

Do not use in animals which are hypovolaemic or show heart block. Use with care in cases with hepatic and or cardiac insufficiency.

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 deep anaesthesia.

4.5 Special precautions for use

Special precautions for use in animals

Direct the spray to the back of the throat.

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

Care should be taken to avoid accidental skin or eye contact. In case of accidental contact, wash the affected area or irrigate the eye with copious amounts of water. Seek medical advice if any adverse effects persist.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Although no safety studies have been conducted with Intubeaze in pregnant queens, data from other species have shown no evidence of harm to the foetus.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

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

Each spray (approximately 0.1-0.2 ml) contains approximately 2-4 mg of lidocaine hydrochloride. (Approximately 72 sprays/vial).

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

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

Maintain a patent airway and support ventilation with oxygen.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Local anaesthesia of the laryngeal mucosa. 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 suseptible than are large fibres and the sensation of pain is the first modality to be lost.

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. Intubeaze has a duration of action of approximately 15 minutes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride Chlorocresol Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

10 ml in a Type 1 glass vial with a mechanical metered-dose applicator. (Approximately 72 sprays/vial).

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Limited Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4004

9. DATE OF FIRST AUTHORISATION

02 Spetmeber 1996

10. DATE OF ANY REVISION OF THE TEXT

September 2015

15 September 2015