ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intubeaze 20 mg/ml laryngopharyngeal spray, solution for cats
Lidocaine hydrochloride monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Lidocaine hydrochloride monohydrate 20 mg/ml

3. PHARMACEUTICAL FORM

Laryngopharyngeal spray, solution.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Cats

6. INDICATION

7. METHOD AND ROUTE OF ADMINISTRATION

Laryngopharyngeal use.
Direct the spray to the back of the throat. It is advisable to cold sterilise the nozzle between uses.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate packaging: 3 months.
Once opened, use by __/__/__

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4093

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intubeaze 20 mg/ml
Laryngopharyngeal spray, solution for cats
Lidocaine hydrochloride monohydrate

2. QUANTITY OF THE ACTIVE SUBSTANCE

20 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE OF ADMINISTRATION

Laryngopharyngeal use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

POM- V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Intubeaze 20 mg/ml laryngopharyngeal spray, solution for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MARKETING AUTHORISATION HOLDER

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

MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intubeaze 20 mg/ml laryngopharyngeal spray, solution for cats
Lidocaine hydrochloride monohydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:
Lidocaine hydrochloride monohydrate 20 mg/ml
(equivalent to lidocaine 16.2 mg/ml)

Excipient:
Chlorocresol 1 mg/ml

A clear, colourless liquid.

4. INDICATION

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

5. 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.

6. ADVERSE REACTIONS

None known.
If you notice any side effects, even those not already listed in this package leaflet or any lack of efficacy, please report via your national reporting system.

7. TARGET SPECIES

Cats.

8. DOSAGE, ROUTE AND METHOD OF ADMINISTRATION

For laryngopharyngeal use.
Give one or two sprays at the back of the throat. 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.

9. ADVICE ON CORRECT ADMINISTRATION

A 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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS:

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Once opened, use within 3 months.

12. SPECIAL WARNINGS

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.

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 accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
None known.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2019

15. OTHER INFORMATION

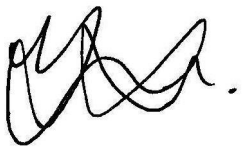
POM-V

For animal treatment only.

To be supplied on veterinary prescription.

Package quantity: 10 ml

Vm 10434/4093



Approved: 08 February 2023