ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intubeaze 20 mg/ml
Oromucosal spray for cats
Lidocaine hydrochloride (Lignocaine hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Lidocaine hydrochloride (Lignocaine hydrochloride) 20 mg
Excipient:
Chlorocresol 1 mg (as an antimicrobial preservative)

3. PHARMACEUTICAL FORM

Oromucosal spray

4. PACKAGE SIZE

10 ml
Approximately 72 sprays/vial.

5. TARGET SPECIES

Cats.

6. INDICATION

To aid intubation in cats.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable for non-food producing animals.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light.
Keep the vial in the outer carton.

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. To be supplied only on veterinary prescription.

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, United Kingdom

16. MARKETING AUTHORISATION NUMBERS

Vm 10434/4004

17. MANUFACTURER'S BATCH NUMBER

Lot:

POM-V Prescription Only Medicine - Veterinarian

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intubeaze 20 mg/ml
Oromucosal spray for cats
Lidocaine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCES

1 ml contains:
Active substance: Lidocaine hydrochloride 20 mg
Excipient: Chlorocresol 1 mg

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

10 ml

4. ROUTE OF ADMINISTRATION

One or two sprays directly to the back of the throat.
Allow 30-90 seconds before attempting intubation.

5. WITHDRAWAL PERIOD

Not applicable for non-food producing animals.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

To be supplied only on veterinary prescription.

POM-V

Vm 10434/4004

Keep out of the sight and reach of children.

Do not store above 25ºC. Protect from light.
Warnings: Read the package leaflet before use.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Intubeaze 20 mg/ml
Oromucosal spray 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
United Kingdom

Manufacturer responsible for batch release:
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 oromucosal spray for cats
Lidocaine hydrochloride (lignocaine hydrochloride)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains:
Active substance: Lidocaine hydrochloride (lignocaine hydrochloride) 20 mg
Excipient: Chlorocresol 1 mg (as an antimicrobial preservative)
A clear solution.

4. INDICATION

To provide 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 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.

6. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For topical application as a metered dose oromucosal spray.
1. Apply one or two sprays directly to the back of the throat.
2. Each spray (approximately 0.1-0.2 ml) contains approximately 2-4 mg of lidocaine hydrochloride.
3. Allow 30-90 seconds before attempting intubation.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25ºC.
Protect from light.

12. SPECIAL WARNINGS

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.

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.

Use during pregnancy or lactation:
Although no safety studies have been conducted with Intubeaze in pregnant females, data from other species have shown no evidence of harm to the foetus.

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

Overdose (symptoms, emergency procedures, antidotes):
Maintain a patent airway and support ventilation with oxygen.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

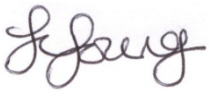
September 2015

15. OTHER INFORMATION

For animal treatment only.
To be supplied only on veterinary prescription.

Vm 10434/4004 | POM-V | Prescription Only Medicine - Veterinarian

UK authorised veterinary medicinal product.
Package quantity: Vials of 10 ml (approximately 72 sprays/vial).

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom

Approved: 22/06/2017