

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intra-Epicaine 20 mg/ml
Solution for injection for horses
Mepivacaine hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Mepivacaine hydrochloride 20 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

6 x 10 ml vials

5. TARGET SPECIES

Horses.

6. INDICATION

For local anaesthesia in horses.

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.
For infiltration: As required, but as a guide, 2-5 ml.
For nerve block: 2-10 ml depending on location.
For intra-articular anaesthesia: 5 ml.
For epidural anaesthesia: 4-10 ml depending on depth and extent of anaesthesia required.

8. WITHDRAWAL PERIOD

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

Observe strict aseptic precautions.

Care should be taken to avoid intra-vascular injection by aspiration prior to and during administration.

User warnings:

Care should be taken to avoid accidental self-injection or skin contact.

In the event of accidental self-injection medical advice should be sought.

Wash splashes from skin or eyes immediately.

10. EXPIRY DATE

EXP:

This product does not contain an antimicrobial preservative. Once opened, use immediately. Discard any unused material.

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. 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 10434/4016

17. MANUFACTURER'S BATCH NUMBER

Lot:

UK: Vm 10434/4016

POM-V

Prescription Only Medicine - Veterinarian

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intra-Epicaine 20 mg/ml
Solution for injection for horses

Mepivacaine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Mepivacaine hydrochloride 20 mg/ml

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

10 ml

4. ROUTE OF ADMINISTRATION

Injection

5. WITHDRAWAL PERIOD

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

UK: Vm 10434/4016

POM-V

Keep out of the sight and reach of children.
Once opened, use immediately. Discard any unused material.
Keep container in the outer carton.
To be supplied only on veterinary prescription.
Read the package leaflet before use.

Dechra Limited, United Kingdom

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
Intra-Epicaine 20 mg/ml
Solution for injection for horses**

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

Manufacturers responsible for batch release:

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

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intra-Epicaine 20 mg/ml solution for injection for horses
Mepivacaine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains:

Active substance:
Mepivacaine hydrochloride 20 mg

Excipients:

Sodium chloride
Water for injections
Sodium hydroxide
Intra-Epicaine is a sterile, clear, colourless isotonic solution.

4. INDICATIONS

Mepivacaine is indicated for infiltration, nerve block, intra-articular and epidural anaesthesia in horses.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient, local soft tissue swelling may occur in a small proportion of cases following injection of the product.

Local anaesthetics used in excess can cause systemic toxicity characteristics by CNS effects.

If systemic toxicity occurs, as a result of inadvertent intra-vascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

Full aseptic precautions should be observed when injecting the product.

For infiltration: As required, but as a guide 2-5 ml.

For nerve block: 2-10 ml depending on location.

For intra-articular anaesthesia: 5 ml.

For epidural anaesthesia:

4-10 ml depending on the depth and extent of anaesthesia required.

In all instances the dosage should be kept to the minimum required to produce the desired effect. The depth and extent of anaesthesia should be determined by pressure with a blunt point, such as the tip of a ball point pen, before commencing manipulations. The duration of action is about 1 hour.

9. ADVICE ON CORRECT ADMINISTRATION

It is recommended that the skin should be shaved and thoroughly disinfected prior to the intra-articular or epidural administration.

10. WITHDRAWAL PERIOD

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

This product does not contain an antimicrobial preservative. Once opened use immediately. Discard any unused material.

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 on that month.

12. SPECIAL WARNINGS

Special precautions for use in animals:

Care should be taken to avoid intra-vascular injection, by aspiration prior to and during administration.

The analgesic effect of mepivacaine, when used as part of a lameness investigation, begins to subside after 45-60 minutes. However, sufficient analgesia may persist to affect gait beyond two hours.

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

Care should be taken to avoid accidental self-injection or skin contact.

In the event of accidental self-injection medical advice should be sought.

Wash splashes from skin or eyes immediately.

Use during pregnancy or lactation:

Not contraindicated.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Local anaesthetics used in excess can cause systemic toxicity characterised by CNS effects.

If systemic toxicity occurs, as a result of inadvertent intra-vascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other veterinary medicinal product.

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

February 2019

15. OTHER INFORMATION

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

UK: Vm 10434/4016	POM-V	Prescription Only Medicine - Veterinarian
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Veterinary medicinal product authorised for use in UK and IE.

Packaging quantities: Glass vials containing 10 ml are available in cartons of six.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

UK: Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom

Approved: 17 April 2019

