ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (10 ml, 5 x 10 ml, 6 x 10 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mepidor 20 mg/ml solution for injection

mepivacaine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Mepivacaine hydrochloride 20 mg
(equivalent to 17.4 mg mepivacaine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
5 x 10 ml
6 x 10 ml

5. TARGET SPECIES

Horses (non-food producing horses)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For infiltration, for perineural, intra-articular and epidural use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not authorised for use in horses producing meat or milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Pregnant women should avoid handling the product. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

VetViva Richter GmbH, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER

Vm 57446/4006

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml clear glass vial type I with bromobutyl rubber stopper and alu-caps

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mepidor 20 mg/ml injection

mepivacaine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

20 mg/ml

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

-

5. WITHDRAWAL PERIOD

-

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Once broached use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Mepidor 20 mg/ml solution for injection

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

Marketing authorisation holder and manufacturer responsible for batch release:
VetViva Richter GmbH,
Durisolstrasse 14,
4600 Wels,
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mepidor 20 mg/ml solution for injection

Mepivacaine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Mepivacaine hydrochloride 20 mg
(equivalent to 17.4 mg mepivacaine)

Clear, colourless to slightly yellow solution

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

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

In case of inadvertent intra-vascular injection or excessive use local anaesthetics can cause systemic toxicity characterised by CNS effects.

If systemic toxicity occurs the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses (non-food producing horses)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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. It is recommended that the skin should be shaved and thoroughly disinfected prior to the intra-articular or epidural administration.

This product does not contain an antimicrobial preservative. Use the vial on one occasion only. Discard any unused material.

9. ADVICE ON CORRECT ADMINISTRATION

See section “Special warnings”.

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.
Not authorised for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
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.
Shelf life after first opening the container: Use immediately

12. SPECIAL WARNING(S)

Special warnings for each target species:
None

Special precautions for use in animals:
Aspirate prior to and during administration to avoid intra-vascular injection.

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 effect gait beyond two hours.

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

- People with known hypersensitivity to mepivacaine or other local anaesthetics of the amide group should avoid contact with the veterinary medicinal product.
- This product may be irritant to the skin and eyes.
- Avoid contact with the skin and eyes. Wash any splashes from skin and eyes immediately with plenty of water. Seek medical advice if irritation persists.
- Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the product.
- Accidental self-injection may result in cardiorespiratory and/or CNS effects. Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive.
- Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Mepivacaine crosses the placenta. There is no evidence that mepivacaine is associated with reproductive toxicity or teratogenic effects. However, there is a potential for anaesthetics of the amide group such as mepivacaine to accumulate in the equine foetus resulting in neonatal depression and interfering with resuscitation efforts. Therefore, use in obstetric anaesthesia only according to the benefit/risk assessment of the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
None known.
Overdose (symptoms, emergency procedures, antidotes):
Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section "Adverse reactions".

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

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
product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

Pack sizes: 10 ml, 5 x 10 ml, 6 x 10 ml.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 25 January 2024