[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mepidor 20 mg/ml solution for injection (BE, IT, UK(NI))

Mepidor vet. 20 mg/ml solution for injection (IS, NO, PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Mepivacaine hydrochloride 20 mg
(equivalent to 17.4 mg Mepivacaine)

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

Clear, colourless to slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses (non-food producing horses)

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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. The veterinary medicinal product should not be administered by pregnant women.
- 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[1], Central nervous system disorder[2], Convulsion[3], Cardiac depression[2,4], Respiratory depression[2,4].

[1] Transient, local soft tissue swelling may occur in a small proportion of cases following injection of the veterinary medicinal product.
[2] In case of inadvertent intra-vascular injection or excessive use local anaesthetics can cause systemic toxicity.
[3] Administration of diazepam should be considered.
[4] Administration of oxygen should be considered.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:
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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Full aseptic precautions should be observed when injecting the veterinary medicinal 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 veterinary medicinal product does not contain an antimicrobial preservative. Use the vial on one occasion only. Discard any unused material.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN01BB03

4.2 Pharmacodynamics

Mepivacaine hydrochloride is a potent local anaesthetic, with a rapid onset of action. Since it does not cause vasodilation it does not require adrenaline to prolong its effect.
The mechanism of action of mepivacaine is to prevent the generation and conduction of the nerve impulse. Conduction is blocked by decreasing or preventing the large transient increase in the permeability of excitable membranes to Na^+ that is produced by a slight depolarisation. This action is due to a direct effect with voltage-sensitive Na^+ channels. Mepivacaine exists in both charged and uncharged forms at physiological pH while the intracellular environment favours formation of the active, charged molecule. The onset of action of mepivacaine is, therefore, rapid (2 - 4 minutes) with an intermediate duration of action (about 1 hour).

4.3 Pharmacokinetics

Peak venous levels of mepivacaine have been measured in mares following caudal epidural anaesthesia or caudal subarachnoid anaesthesia. The maximum venous concentrations were similar

(0.05 µg/ml) and were reached in 51 - 55 minutes. In a separate study, mepivacaine or its metabolites appeared in the urine within 15 minutes of subcutaneous injection and reached peak levels within 2 - 6 hours. It was largely cleared from the urine within 24 hours. The major metabolite in horse urine is 3-hydroxymepivacaine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.
This veterinary medicinal product does not contain an antimicrobial preservative.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

Cardboard box with clear glass vials type I, bromobutyl rubber stopper or bromobutyl stopper with a fluorinated polymer coating and aluminium cap.

Pack sizes: 10 ml, 5 x 10 ml, 6 x 10 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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
(BE, IT, UK(NI))

Mepidor vet. 20 mg/ml solution for injection
(IS, NO, PT)

Mepivacaine hydrochloride

Comentado [AW1]: The applicant kindly asks for the addition of the active substance in section 1. This useful information will be stated on the main panel of the cardboard box.

2. STATEMENT OF ACTIVE SUBSTANCES

Mepivacaine hydrochloride 20 mg/ml

3. PACKAGE SIZE

10 ml
5 x 10 ml
6 x 10 ml

4. TARGET SPECIES

Horses (non-food producing horses)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

The veterinary medicinal product should not be administered by pregnant women.
Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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 (BE, IT, UK(NI))
Mepidor vet. (IS, NO, PT)

Horses (non-food producing)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Mepivacaine hydrochloride 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

10 ml

VetViva Richter (logo)

Comentado [AW2]: The applicant kindly asks to include the pack size and VetViva Logo for additional information as per Article 13 of Regulation 2019/6, requested for all concerned member states.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Mepidor 20 mg/ml solution for injection (BE, IT, UK(NI))

Mepidor vet. 20 mg/ml solution for injection (IS, NO, PT)

2. Composition

Each ml contains:

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

Clear, colourless to slightly yellow solution

3. Target species

Horses (non-food producing horses)

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:
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 veterinary medicinal 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. The veterinary medicinal product should not be administered by pregnant women.
- 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 related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section "Adverse reactions".

<Special restrictions for use and special conditions for use:>

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

7. Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data):
Injection site swelling[1], Central nervous system disorder[2], Convulsion[3], Cardiac depression[2,4], Respiratory depression[2,4].

[1] Transient, local soft tissue swelling may occur in a small proportion of cases following injection of the veterinary medicinal product.
[2] In case of inadvertent intra-vascular injection or excessive use local anaesthetics can cause systemic toxicity.
[3] Administration of diazepam should be considered.
[4] Administration of oxygen should be considered.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Full aseptic precautions should be observed when injecting the veterinary medicinal 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 veterinary medicinal 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 periods

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 immediate packaging: Use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes: 10 ml, 5 x 10 ml, 6 x 10 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>

<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse events>:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

<Local representatives <and contact details to report suspected adverse events>:>

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

17. Other information