SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mepidor 20 mg/ml solution for injection

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 the marketing authorisation holder 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 IMMUNOLOGICAL 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.

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

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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
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

Vm 57446/4006

8. DATE OF FIRST AUTHORISATION

4 October 2016

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 13 February 2026