SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mepivacaine Richter 20 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to slightly yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Horse

4.2 Indications for use, specifying the target species

Mepivacaine is indicated for intra-articular and epidural anaesthesia in horses.

4.3 Contraindications

Do not use in cases of known hypersensitivity to local anaesthetics belonging to the amide group, or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 affect 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 an 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

Mepivacaine should be used carefully in patients undergoing treatment with other local anaesthetics of the amide group since the toxic effects are additive.

4.9 Amounts to be administered and administration route

Full aseptic precautions should be observed when injecting the product.

For intra-articular anaesthesia:	60-600mg of mepivacaine hydrochloride (3 to 30 ml of the medicinal product), dependent on joint size
For epidural use:	0.2 – 0.25 mg/kg (1.0 to 1.25 ml/100 kg), up to10 ml/horse, 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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section 4.6.

4.11 Withdrawal period(s)

Meat and offal:	3 days
Milk:	72 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: local anaesthetics, amides
ATC vet code: QN01BB03

5.1 Pharmacodynamic properties

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. The onset of action of mepivacaine is, therefore, rapid (2-4 minutes) with an intermediate duration of action (about 1 hour).

5.2 Pharmacokinetic particulars

Peak plasma concentrations of mepivacaine have been measured in mares following caudal epidural anaesthesia or caudal subarachnoid anaesthesia. The maximum plasma concentrations were similar (0.05 µg/ml) and were reached in 51-55 minutes. The major metabolite in horse urine is 3-hydroxymepivacaine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

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

6.4 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.

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH
Durisolstrasse 14
4600 Wels
Austria

8. MARKETING AUTHORISATION NUMBER

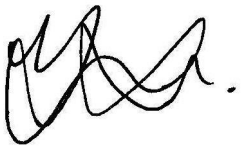
Vm 57446/4009

9. DATE OF FIRST AUTHORISATION

15 November 2017

10. DATE OF REVISION OF THE TEXT

January 2022



Approved: 23 January 2023