SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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

Horses (non-food producing horses)

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance 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 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.
- 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.
- 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

Mepivacaine crosses the placenta. There is, however, no evidence that mepivacaine is associated with reproductive toxicity or teratogenic effects.
The safety of the veterinary medicinal product has not been established during lactation.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

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)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: local anaesthetics, amides
ATCvet 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. 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).

5.2 Pharmacokinetic particulars

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.

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 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: 30 months.

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

Richter Pharma AG
AUSTRIA

8. MARKETING AUTHORISATION NUMBER

Vm 22080/4008

9. DATE OF FIRST AUTHORISATION

04 October 2016

10. DATE OF REVISION OF THE TEXT

October 2016

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