Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Mepiblock 20 mg/ml solution for injection for horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Mepivacaine (as hydrochloride) 17.42 mg
Equivalent to 20 mg of mepivacaine hydrochloride

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution, practically free from visible particles.

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.
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

Care should be taken to avoid intra-vascular injection, by aspiration prior to and during administration.
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

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.
Adverse effects in the foetus cannot be excluded. Pregnant women should avoid handling the veterinary medicinal product.
People with known hypersensitivity to mepivacaine or other local anaesthetics of the amide group should avoid contact with the veterinary medicinal product.
The product may be irritant to the skin and eyes.
Avoid contact with skin and eyes. Wash splashes from the skin and eyes immediately with plenty of water. Seek medical advice if irritation persists.
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.

Local anaesthetics used in excess can cause systemic toxicity characterised by CNS effects.

If systemic toxicity occurs as a result of inadvertent intra-vascular injection, 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 during pregnancy and for obstetric anaesthesia only according to the benefit/risk of the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

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 use: 3 to 30 ml dependent on joint size.

For epidural use: 0.2 to 0.25 mg/kg (1.0 to 1.25 ml/100 kg), up to a maximum of 10 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 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 intra-articular or epidural administration.

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

The risk of experiencing adverse effects (see section 4.6) may increase when overdosing.

4.11 Withdrawal period(s)

Meat and offal: 2 days.
Milk: 2 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Local anaesthetic, mepivacaine.
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. 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 plasma concentrations of mepivacaine have been measured in mares following caudal epiduralanaesthesia or caudal subarachnoid anaesthesia. The maximum venousconcentrations were similar (0.05 µg/ml) and were reached in 51-55 minutes. 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
Water for injections
Sodium hydroxide (for pH adjustment)

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life of the veterinary medicinal product after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and composition of immediate packaging

Clear type I glass vials containing 10 ml, with a red chlorobutyl rubber stopper and aluminium seals, available in cartons of six.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA22622/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 December 2017

10 DATE OF REVISION OF THE TEXT

January 2019