[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intra-Epicaine 20 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Mepivacaine hydrochloride 20 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Water for injections
Sodium hydroxide

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

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For infiltration, nerve block, intraarticular and epidural anaesthesia in horses.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Care should be taken to avoid intravascular 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 affect 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 or skin contact.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash splashes from skin or eyes immediately.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site swelling[a]; Central nervous system disorder[b], convulsion[c]; Cardiac depression[c]; Respiratory depression[c].

[a] Transient.
[b] Local anaesthetics used in excess can cause systemic toxicity characterised by CNS effects.
[c] If systemic toxicity occurs as a result of inadvertent intravascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions 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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Infiltration, perineural use, epidural use and intraarticular use.

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 intraarticular 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 intraarticular or epidural administration.

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

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

If systemic toxicity occurs as a result of inadvertent intravascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

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

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Not authorised for use 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.

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. Mepivacaine has been employed successfully for all types of local anaesthesia and is recommended for infiltration, nerve block, intraarticular and epidural anaesthesia in the horse.
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 other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

This veterinary medicinal product does not contain an antimicrobial preservative. Once opened, use immediately. Discard any unused material.

5.3 Special precautions for storage

Do not store above 25 ºC.

5.4 Nature and composition of immediate packaging

Clear glass vials containing 10 ml, with a red chlorobutyl stopper and aluminium flip cap, are available in cartons of six.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22622/013/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 01 December 2006

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

April 2026.

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).