

[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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 characteristics 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

Not contraindicated.

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.

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

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.

4.11 Withdrawal period

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.

5. PHARMACOLOGICAL 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. Mepivacaine has been employed successfully for all types of local anaesthesia and is recommended for infiltration, nerve block, intra-articular and epidural anaesthesia in the horse.

ATCvet Code: QN01BB03

5.1 Pharmacodynamic properties

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
Water for injections
Sodium hydroxide

6.2 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.

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

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

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBERS

UK: Vm 10434/4016
IE: VPA 10799/001/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

UK: 20 December 2005
IE: 30 September 2011

10. DATE OF REVISION OF THE TEXT

August 2015