mepidor® 20mg/ml

Solution for Injection
Mepivacaine hydrochloride

Statement of the active substances and other ingredients
Each ml contains:

Active substances:
Mepivacaine hydrochloride 20mg
(equivalent to 17.4 mg mepivacaine)

Clear, colourless to slightly yellow solution.

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

Contraindications
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Adverse reactions
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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Target species
Horses (non food producing horses).

Dosage for each species, routes and method of administration
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.

Advice on correct administration
See special warning(s).

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.

Not authorised for use in horses producing milk for human consumption.

Special storage precautions
Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Shelf life after first opening the container: Use immediately.

Special warning(s)
Special warnings for each target species: None.

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.

Use during pregnancy and lactation:
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section "Adverse reactions".

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

Special precautions for the disposal of unused product or waste materials, if any
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved
27/07/2016

Other Information
Pack size 10ml, 5 x 10ml, 6 x 10ml.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

To be supplied only on veterinary prescription.

For animal treatment only.

Marketing authorisation holder:
Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria

Manufacturer responsible for batch release:
Richter Pharma AG, Durisolstrasse 14, 4600 Wels, Austria

Distributed by:
Animalcare Limited, 10 Great North Way, York, YO26 6RB, UK

Vm 22080/4008

POM-V

60706/A

innovativegraphics

CLIENT Animalcare

DESCRIPTION Mepidor 20ml/mg_PIL

JOB NO 1728

DATE 19 July 2016

VERSION Version 11

DATE 4 October 2016

NOTES Scale: Actual size

Pantone Black

Minimum typesize 9pt

SIZE IN MM: A5

RICHTER PHARMA VERSION NUMBER: 60706/A

DATE AND HOUR OF LAST CHANGE: 4 October 2016/1.00

1cm 2cm 3cm 4cm