SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Pethidine 50 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Pethidine hydrochloride	5.0 % w/v

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats, dogs and horses.

4.2 Indications for use, specifying the target species

For use as a sedative analgesic in dogs and cats, and as an analgesic for the symptomatic relief of pain in spasmodic colic in horses.

4.3 Contraindications

Do not use in cases where renal function is impaired.
Do not use in horses with obstructive colic.

4.4 Special warnings for each target species

Do not use in horses with obstructive colic.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not administer by the intravenous route. Intravenous injection may result in CNS stimulation and convulsions. These effects may be controlled by Diazepam or Pentobarbitone injection.
Do not exceed stated dose.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Following accidental self-injection or ingestion, seek medical advice taking the vial with you.

Following eye contamination or excessive skin contact, irrigate/wash thoroughly with cold running water. Seek medical advice if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

Respiratory depression may be controlled by Narlorphine Hydrochloride.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use with Detomidine.

4.9 Amounts to be administered and administration route

Cats and dogs:
By intramuscular injection (3.3 mg/kg body weight) for premedication, prior to surgical procedures and examinations, as an adjunct to sedation or anaesthesia, or post operatively as an analgesic.

Horses:
By intramuscular injection (2.0 mg/kg body weight) for the relief of pain in spasmodic colic.

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

May result in CNS stimulation and convulsions, which may be controlled by Diazepam or Pentobarbitone injection.

4.11 Withdrawal periods

Not authorised for use in horses intended for human consumption.

5. PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: Opioid derivatives
ATC Vet Code: QN02AB02

5.1 Pharmacodynamic properties

Pethidine is a synthetic opioid analgesic, which originates as a fine white crystalline powder that is very soluble in water.

Pain relief is achieved without loss of consciousness, muscular activity, coordination or responsiveness of the senses.

5.2 Pharmacokinetic properties

Pethidine produces prompt, short acting analgesia, which also exerts an antispasmodic action on the smooth muscle of the large intestine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Water for injections

6.2 Incompatibilities

Do not use with Detomidine.

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 1 month.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of immediate packaging

Multidose 50 ml vial of type I clear glass with a red chlorobutyl rubber plug, containing a clear, colourless, aqueous solution.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product must be destroyed in accordance with the Misuse of Drugs Act. Any waste material 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 NUMBER

Vm 10434/4031

9. DATE OF FIRST AUTHORISATION

18 August 1993

10. DATE OF ANY REVISION OF THE TEXT

November 2015


03 November 2015