

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pethidine
50 mg/ml
Solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Active substance:
Pethidine hydrochloride 5.0% w/v

Excipient:
Chlorocresol 0.1% w/v

4. PHARMACEUTICAL FORM

Solution for injection. Clear, colourless, aqueous solution.

5. PACKAGE SIZE

50 ml

6. INDICATION(S)

Pethidine injection is recommended 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.

7. CONTRAINDICATIONS

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

8. ADVERSE REACTIONS

Respiratory depression may be controlled by nalorphine hydrochloride.

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

9. TARGET SPECIES

Cats, dogs and horses.

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dogs and Cats 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.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Do not use after the expiry date stated on the label.

14. SPECIAL WARNING(S)

Special precautions for use in animals:

Do not administer by the intravenous route.

Overdosage or intravenous injection may result in CNS stimulation and convulsion.

These effects may be controlled by diazepam or pentobarbitone injection.

Do not exceed the stated dose.

Care should be taken with concomitant use of sedatives, analgesics and depressants as the depressant effects may be potentiated.

Appropriate dose adjustments should be made.

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.

Use during pregnancy or lactation:

Do not use in pregnant animals.

Interaction with other medicinal products and other forms of interaction:

Do not use with detomidine.

Overdose (symptoms, emergency procedures, antidotes):

May result in CNS stimulation and convulsion, which may be controlled by diazepam or pentobarbitone injection.

Incompatibilities:

Do not use with detomidine.

15. EXPIRY DATE

Once broached, use by ____ / ____ / ____
Discard unused material.

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Destroy any unused product must be destroyed in accordance with the Misuse of Drugs Act.

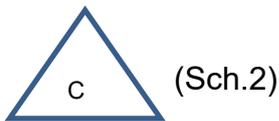
Dispose of any part-used and empty containers in accordance with guidance from your local waste authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

3 November 2015

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.



POM-V

Prescription Only Medicine – Veterinarian

Pethidine injection is a schedule 2 controlled drug.

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4031

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION

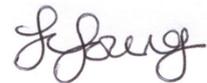
Package quantity: Multidose vial containing 50 ml.

Pethidine injection has been used successfully in combination with acetyl promazine for sedation in dogs and cats.

Local Representative:

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.

Approved: 28/06/2017

A handwritten signature in black ink, appearing to read 'J. Long', is positioned below the approval date.