PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pentoject Pentobarbitone Sodium 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Pentobarbitone Sodium 200 mg/ml, Tartrazine 1409 (E102) 0.04 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100ml
250ml
500ml

5. TARGET SPECIES

Dogs, cats other small animals and mink

6. INDICATION(S)

Use: For euthanasia in dogs, cats, other small animals and mink.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: To effect, usually 0.4ml/kg in debilitated or elderly animals, 0.6-0.8 ml/kg in younger or more fit animals, preferably by rapid intravenous injection.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications, warnings etc: Not for use in animals intended for human or animal consumption. Not for use in anesthesia. The warnings and contra-indications within the package leaflet must be read before use. In the event of accidental self-administration, by injection or skin absorption, seek URGENT medical attention, advising medical services of barbiturate poisoning and show this advice.

10. EXPIRY DATE

Following withdrawal of the first dose, use the product within 28 days. This product does not contain any antimicrobial preservative. Destroy any unused product in accordance with the misuse of drugs regulations (2001).

EXP:
Date to discard:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.
Discard unused material. Discard container if any sediment is observed,

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

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

POM-V

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 32742/4033

17. MANUFACTURER'S BATCH NUMBER

Lot:

[Include information under these headings as it appears in the SPC]
PACKAGE LEAFLET FOR:

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

Marketing authorisation holder:
Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium

Site of batch release:
Produlab B.V.
Forellenweg 16
Ramsdonksveer
4941SJ
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pentoject Pentobarbitone Sodium 200 mg/ml Solution for Injection
Pentobarbital sodium

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

Presentation: The product is a clear yellow, non-sterile solution for injection presented in a multi-dose amber bottle.

Each ml contains:
ACTIVE INGREDIENT
Pentobarbitone Sodium 200 mg
OTHER INGREDIENTS
Tartrazine 1409 (E102) 0.04 mg

4. INDICATION(S)

For euthanasia in dogs, cats, other small animals and mink

5. CONTRAINDICATIONS

Contra-indications, warnings: Not for use in anaesthesia. Not for use in animals intended for human or animal consumption.

6. ADVERSE REACTIONS

Undesirable effects: Body spasms may occur in some animals, which may distress observers. Very low frequency when an appropriate dose is used and administered rapidly.

7. TARGET SPECIES

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

Dosage and Administration: To effect by rapid intravenous injection, usually 0.4ml/kg in debilitated or elderly animals, or 0.6-0.8ml/kg in younger or fit animals. These dosages correspond to 80mg/kg or 120-160mg/kg, respectively. The intravenous route of administration should be the route of choice if possible but alternatives such as intraperitoneal or intramuscular are available when venepuncture is difficult to achieve (e.g. in cats). In some circumstances the intrathoracic route may be used but this is usually the last resort. There is a risk of injection into the lungs, which causes coughing and distress.
Direct injection into a chamber of the heart is rapid but it may be difficult to accurately locate the heart chamber in larger dogs and repeated attempts could cause unnecessary pain and distress.

9. ADVICE ON CORRECT ADMINISTRATION

Treatment of overdosage: If accidently administered to an animal not presented for euthanasia, care should be aimed at supporting the respiratory and cardiovascular systems. Use of artificial respiration, oxygen and analeptics are appropriate.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
Do not store above 25^{o}C. Protect from light.
The product does not contain an antimicrobial preservative.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Following withdrawal of the first dose use within 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life, the date on which any product remaining in the container should be discarded should be worked out. The discard date should be written in the space provided on the label.
Discard unused material. Discard container if any sediment is observed.

12. SPECIAL WARNING(S)

Precautions and warnings: For animal treatment only. In the event of accidental self-administration, by injection of skin absorption, seek urgent medical attention, advising medical service of barbiturate poisoning and show this advice.

This is a potent drug, which is toxic in man. Particular care should be taken to avoid accidental ingestion and self-injection. In the event of an accident the following actions should be taken:

Skin-Wash immediately with water and then thoroughly with soap and water.

Eyes- Wash immediately with cold water and obtain medical advice.

Ingestion- Obtain medical attention immediately. Wash out mouth. Keep warm and rest.

Accidental self-injection- Obtain URGENT medical attention advising medical services of barbiturate poisoning. Do not leave patient unattended.

Advice to doctor- Maintain airways and give symptomatic and supportive treatment.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Destroy any unused product in accordance with the misuse of Drugs Regulations (2001). Dispose of any part-used and empty containers in accordance with guidance from your local waste regulation authority.

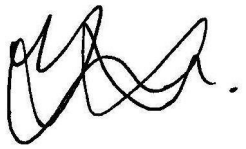
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

To be supplied only on veterinary prescription. UK authorised veterinary medicinal product.
Pack sizes: 100 ml, 250 ml and 500 ml vials
Not all pack sizes may be marketed

POM-V



Approved: 11 August 2022