MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

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

Fort Dodge Animal Health Southampton SO30 4QH

Marketing Authorisation Holder: Ayrton Saunders, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU

Manufactured by Pharmasol Ltd., North Way, Andover SP10 5AZ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lethobarb ® 20% w/v Solution for Injection Pentobarbital Sodium

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

Each ml contains 200mg Pentobarbital Sodium.
Patent Blue V (E131) 0.0006% w/v.

4. PHARMACEUTICAL FORM

5. PACKAGE SIZE

6. INDICATION(S)

For euthanasia of domestic pets and smaller farm animals.

7. CONTRAINDICATIONS

Not to be used for anaesthesia.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Domestic pets and smaller farm animals

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

Recommended Dosage Schedule: By rapid intravenous injection at the rate of 0.7ml/kg body weight equivalent to 140mg pentobarbital sodium per kg bwt. Death will follow quickly as the result of irreversible anaesthesia.

11. ADVICE ON CORRECT ADMINISTRATION

When it is predicted that euthanasia may be problematical (e.g. aggressive patients) it is recommended that premedication with an appropriate sedative is given. 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 a 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 chambers in larger dogs and repeated attempts could cause pain and distress. The animal should be restrained in order to forestall narcotic excitement until anaesthesia supervenes. This is particularly important with cats.

12. WITHDRAWAL PERIOD

Not to be used in animals intended for human consumption. Treated horses may never be slaughtered for human consumption. The horses must have been declared as not intended for human consumption under national horse passport legislation. Carcasses of animals which have been euthanased with this product must not be used for animal consumption.

13. SPECIAL STORAGE PRECAUTIONS

This product is not sterile. Do not store above 25°C.
Following withdrawal of the first dose use the product within 28 days.

Discard unused material. (Date of discard ……../……../……..)
Discard if any sediment is observed.
When the container is broached (opened for the first time), using the in-use shelf-life specified, the date on which any product remaining in the container should be worked out. This discard date should be written in the place provided.

14. SPECIAL WARNING(S)

User Warnings: Pentobarbital is a potent hypnotic and sedative (Schedule 3 Controlled Drug). It is toxic if swallowed and can be absorbed through the skin. **This is a potent drug, which is toxic to man. Particular care should be taken to avoid accidental ingestion and self-injection.** In the event of accidental self-administration by injection or skin absorption, seek URGENT medical attention, advising medial service or barbiturate poisoning. Peel off front label for full user warnings.
Further user warnings: In the event of accident the following action should be taken:
Skin: wash immediately with water and then thoroughly with soap and water.

Eyes: wash immediately with cold water and obtain medical attention.
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 the patient unattended.

Advice to Doctor: Maintain airways and give symptomatic and supportive treatment. The concentration of pentobarbital in this product is such that accidental ingestion or injection of quantities as small as 2ml in human adults can have serious CNS effects. A dose of Pentobarbital Sodium of 1g (equivalent to 5ml of product) has been reported to be fatal in humans, in certain circumstances. In the event of accidental administration to an animal not presented for euthanasia, measures such as artificial respiration, administration of oxygen and the use of analeptics are appropriate.

15. EXPIRY DATE

Coded on during production.

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

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

November 2022

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

Sch 3 CD Toxic

CD

POM-V

To be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 16431/3000

21. MANUFACTURER'S BATCH NUMBER

Coded on during production.

Approved: