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

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pentobarbital for Euthanasia 20% w/v Solution for Injection

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

Pentobarbital Sodium

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

4. PHARMACEUTICAL FORM

Non-sterile solution for injection.

5. PACKAGE SIZE

100ml

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 raid, but it may be difficult to accurate 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 or animal consumption. Treated horse may never be slaughtered for human consumption. The horses must have been declared as not for human consumption under national horse passport legislation.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. The product is not sterile.

Following withdrawal of the first dose, use the product within 28 days.

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 space provided.

Discard unused material. (Date of discard ……./……./…….)

Discard if any sediment is observed.

14. SPECIAL WARNING(S)

User Warnings: This is a potent drug, which is toxic to man. Particular care should be taken to avoid accidental ingestion and self-injection. Pentobarbital is a potent hypnotic and sedative (Sch 3 CD). It is toxic if swallowed and can be absorbed through the skin.

In the event of accidental self-administration by injection or skin absorption, seek URGENT medical attention, advising medial service or barbiturate poisoning.
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 the product is such that the 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 5ml or 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

Carcasses of animals which have been euthanased with this product must not be used for animal consumption. 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

FOR ANIMAL TREATMENT ONLY.

To be supplied only on veterinary prescription.

POM-V	CD	Toxic Sch 3 CD

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

Keep out of reach and sight of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 16431/3001

21. MANUFACTURER'S BATCH NUMBER

Coded on during production.

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

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pentobarbital for Euthanasia 20% w/v Solution

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

Non-sterile solution for injection

5. PACKAGE SIZE

500ml

6. INDICATION(S)

For euthanasia of large animals

7. CONTRAINDICATIONS

Not to be used for anaesthesia.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Large 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 appropriate sedative is given. The intravenous route of administration should be the route of choice if possible, but alternative such as intraperitoneal or intramuscular are available when venepuncture is difficult to achieve, e.g. in cats. In some circumstances intrathoracic route may be used but this is 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 hear 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 horse 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

Do not store above 25°C. The product is not sterile.

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 discarded should be worked out. The discard date should be written in the space provided.
FOLLOWING WITHDRAWAL OF THE FIRST DOSE USE THE PRODUCT WITHIN 28 DAYS, DISCARD UNUSED MATERIAL.

(ONCE BROACHED (OPENED) USE BY ……/……../……..)

14. SPECIAL WARNING(S)

User Safety Warnings

Pentobarbital is a potent hypnotic and sedative (CD Sch 3). 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 the medical service of barbiturate poisoning. In the event of an 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 at rest. Administer symptomatic and supportive measures
ACCIDENTAL SELF INJECTION AND OTHER HUMAN INNOCULATION: Seek 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 the product is such that accidental injection or ingestion 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 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 any part used product and empty containers in accordance with guidance for appropriate waste regulatory 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

FOR ANIMAL TREATMENT ONLY.

To be supplied only on veterinary prescription.

POM-V	CD	TOXIC Sch 3 CD

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 16431/3001

21. MANUFACTURER'S BATCH NUMBER

Coded during production

Approved: