SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pentobarbital for Euthanasia 20% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)	**% w/v**
Pentobarbital Sodium	20.00

Excipients	
Patent Blue V (E131)	0.0006

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear blue liquid

4. CLINICAL PARTICULARS

4.1 Target species

Domestic pets and smaller farm animals, mink and large animals

4.2 Indications for use, specifying the target species

100ml pack: for euthanasia of domestic pets and smaller farm animals.
500ml pack: for euthanasia of mink and large animals

4.3 Contraindications

Not to be used for anaesthesia

4.4 Special warnings for each target species

4.5 Special precautions for use

i) Special precautions for use in animals

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.

ii) Special precautions for the person administering the veterinary medicinal product to animals

Pentobarbital is a potent hypnotic and a 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 medical service of 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 patients unattended.

Advice to Doctor – Maintain airways and give symptomatic and supportive treatment.

The concentration of Pentobarbital in the product is such that the 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.

iii) Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Normally, very rapid onset of anaesthesia, respiratory depression, cardiac arrest and death occurs following intravenous administration. Very occasionally one or a few gasping respirations occur after cardiac arrest. At this stage the animal is already clinically dead.

4.7 Use during pregnancy, lactation or lay

The rapid administration of the recommended dose will achieve the desired effects of euthanasia.

4.8 Interaction with other medicinal products and other forms of interaction

The product is intended for use alone for rapid smooth induction of euthanasia There is no necessity or likelihood of concomitant drug use.

When an aggressive animal is to undergo euthanasia, premedication with a more easily administered (oral, subcutaneous or intramuscular) sedative is recommended. Such a product will have no deleterious effects upon the subsequently administered barbiturate.

4.9 Amount(s) to be administered and administration route

By rapid intravenous injection at the rate of 0.7ml/kg bodyweight, equivalent to 140mg pentobarbital sodium per kg bwt. Death will result quickly as the result of irreversible anaesthesia.

The intravenous route of administration should be the route of choice if possible, but alternatives such as intraperitoneal or intramuscular are available when venipuncture 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 unnecessary pain and distress. The animal should be restrained in order to forestall narcotic excitement until anaesthesia supervenes. This is particularly important with cats.

When it is predicted that euthanasia may be problematical (e.g. aggressive patients) it is recommended that premedication with an appropriate sedative is given.

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

Not applicable

4.11 Withdrawal period

The product is intended for euthanasia on the grounds of animal welfare to prevent (further) unnecessary suffering.

Not to be used in animals intended for human or animal 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 legislation. There is no withdrawal period for such a product.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Active Substance

Pentobarbital sodium is an oxybarbiturate derivative of Barbituric Acid. Barbiturates depress the entire central nervous system but, quantitatively, various areas are affected differently. The immediate effect is the unconsciousness of deep anaesthesia followed by rapid death in overdose. The normal anaesthetic dose if 30mg/kg. The dose for euthanasia is 140mg/kg, represented in this product by a dose of 0.7ml/kg.

ATC Vet Code: QN51AA01

5.1 Pharmacodynamic properties

Pentobarbital is a potent hypnotic and sedative (Schedule 3 CD).
The product acts by direct action upon the medulla resulting, at such a high dose rate, in rapid depression of the respiratory centre. Breathing stops and cessation of heart action quickly follows.

5.2 Pharmacokinetic properties

When injected into the bloodstream, a barbiturate ionises, the degree depending on the dissociation constant of the agent and the pH of the blood. Barbiturates bind with plasma proteins, forming an equilibrium of bound and unbound drug in circulating blood. Cell penetration can only occur with the undissociated form. After cell penetration, dissociation again occurs and binding of the drug to intracellular organelles takes place.
Tissue changes due to cellular penetration and intracellular binding have not been described. In general, the effects on tissues can be categorised as direct and indirect. In general, these effects are subtle and little is known concerning them.

Since the purpose of this drug is the proven smooth induction and rapid progress to euthanasia, other aspects of its absorption, distribution, biotransformation and elimination are not appropriate to this licence application.

Following intracardiac use unconsciousness is almost immediate and cardiac arrest follows within 10 seconds.

Following intravenous use unconsciousness follows in 5 -10 seconds after

completion of administration

Death follows 5 - 30 seconds later. Intraperitoneally, euthanasia is achieved in 3 - 10 minutes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Propylene Glycol
Water Purified

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 Years.
Shelf life after opening the immediate packaging: 28 days

6.4 Special precautions for storage

This product is not sterile.
Following withdrawal of first dose, use the product within 28 days. Discard unused material.
Discard if any sediment is observed.
The product is a Schedule 3 Controlled Drug
Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

100 ml amber Type III glass vial with rubber butyl bung secured with aluminium overseal.

500 ml amber Type III glass bottle with pierced screw cap with butyl rubber wad.

Not all pack sizes may be marketed.

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 disposed of in accordance with the Misuse of Drugs Regulations 2001.
Any waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Ayrton Saunders Limited
9 Arkwright Road
Astmoor Industrial Estate
Runcorn
Cheshire
WA7 1NU

8. MARKETING AUTHORISATION NUMBER(S)

Vm 16431/3001

9. DATE OF FIRST AUTHORISATION

31 August 1993

10. DATE OF REVISION OF THE TEXT

November 2022