SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pentoject, Pentobarbitone Sodium 200 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance(s)

Pentobarbitone Sodium	200 mg

Excipients

Tartrazine 1409 (E102)	0.04 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

A clear, yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, other small animals, and mink.

4.2 Indications for use, specifying the target species

Euthanasia in the target species.

4.3 Contraindications

Not for use in anaesthesia.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

Use only for euthanasia.

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

In the event of accidental self-administration, by injection or skin absorption, seek URGENT medical attention advising the medical services 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 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 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. This product is not sterile.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.9 Amount(s) to be administered and administration route

To effect, usually 0.4 ml/kg in debilitated or elderly animals, or 0.6-0.8 ml/kg in younger or more fit animals. These dosages correspond to 80 mg/kg or 120-160 mg/kg, respectively. Preferably by rapid intravenous injection.

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.

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

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

If accidentally 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.

4.11 Withdrawal period(s)

Not for use in animals intended for human or animal consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Barbiturates **ATC Vet Code:** QN51AA01

5.1 Pharmacodynamic properties

Pentobarbitone Sodium is a barbiturate. Injection of lethal doses causes progressive depression of the central nervous system, which may be considered as passing through the following sequential phases: i) sedation, ii) intoxication, possibly with involuntary
excitement, iii) anaesthesia, (iv) respiratory arrest and subsequent cardiac failure.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartrazine 1409 (E102) Glycerol
Industrial Methylated Spirit
Water for Injections

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must

not be mixed with other veterinary medicinal products.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25ºC. Protect from light.
This product does not contain any antimicrobial preservative.
Following withdrawal of the first dose use within 28 days. Discard unused material.
Discard container if any sediment is observed,

6.5 Nature and composition of immediate packaging

100 ml, Amber, Type II glass vial with a centre-hole aluminium seal and a bromobutyl rubber bung.
250 ml, Amber, Type II glass vial with a centre-hole aluminium seal and a bromobutyl rubber bung.
500 ml, Amber, Type II glass vial with an aluminium over seal and a bromobutyl rubber bung.
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 destroyed in accordance with the Misuse of Drugs Regulations (2001).
Any waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 32742/4033

9. DATE OF FIRST AUTHORISATION

21 October 1993

10. DATE OF REVISION OF THE TEXT

June 2024

Gavin Hall

Approved 27 June 2024