Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

EUTHATAL solution for injection 200 mg in 1 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Pentobarbital sodium	200	mg

Excipients

Patent Blue V (E131)	0.01	mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Blue aqueous solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, cats and other small animals.

4.2 Indications for use, specifying the target species

Euthanasia in dogs, cats and other small animals.

4.3 Contraindications

Do not use for anaesthetic purposes.
Carcasses of animals, which have been euthanased with the product, must not be used for animal consumption.
Do not administer by intramuscular route.

4.4 Special warnings for each target species

In some circumstances the intrathoracic or intracardiac routes of administration may be used, but only as a last resort. The choice of these routes should be made in the light of the attendant difficulties and the unnecessary pain and distress to the animal which could result. When it is anticipated that euthanasia may be problematical (e.g. aggressive patients), premedication with appropriate sedative is recommended.

4.5 Special precautions for use

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-administration, seek urgent medical attention, advising medical service of barbiturate poisoning. Pentobarbital 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

Not applicable.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

None known. The product is intended for use alone.

4.9 Amounts to be administered and administration route

The product is primarily intended for, and is most consistently effective when administered by intravenous route.The solution should be administered at the rate of 1ml per 1.4kg (3lb) bodyweight (approximately 150mg/kg bodyweight) as quickly as possible.

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

Not applicable.

4.11 Withdrawal period(s)

Not to be used in animals intended for animal or human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC code: QN51AA01

5.1 Pharmacodynamic properties

The major action of barbiturates is to depress the central nervous system (CNS). All degrees of depression, ranging from mild sedation to general anaesthesia and ultimately death are induced depending upon dosage. The dosage for euthanasia is 140-150 mg/kg, death occurs due to respiratory failure.

5.2 Pharmacokinetic particulars

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Ethanol

Patent Blue V (E131)
Water for Injections

6.2 Major incompatibilities

Do not dilute with water or any other fluid.

6.3 Shelf-life

3 years.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
Discard if any sediment is observed.
The product does not contain an antimicrobial preservative.
This product is not sterile.

6.5 Nature and composition of immediate packaging

Amber, Type II vials with rubber (6BU) chlorobutyl bung containing 100ml

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10791/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 October 1995
Date of last renewal: 30 September 2010

10 DATE OF REVISION OF THE TEXT

August 2019