

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthasol vet. 400 mg/ml, solution for injection (AT, BE, DK, EE, EL, FI, IE, IS, LT, LU, LV, NO, PL, RO SE, UK)

Euthasol 400 mg/ml, solution for injection (ES, PT)

Euthasol vet. solution for injection (FR)

Euthasol vet. 400 mg/ml solution for injection for dogs, cats, rodents, rabbits, cattle, sheep, goats, horses and mink (IT)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

**Active substance:**

Pentobarbital (as sodium salt) 362.9 mg  
(equivalent to 400 mg pentobarbital sodium)

**Excipient(s):**

Benzyl alcohol (E1519)	20 mg
Patent Blue V (E131)	0.01 mg

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Solution for injection.  
Clear blue liquid.

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Dogs, cats, rodents, rabbits, cattle, sheep, goats, horses and mink.

#### 4.2 Indications for use, specifying the target species

Euthanasia

#### 4.3 Contraindications

**Do not use** for anaesthesia.

#### **4.4 Special warnings for each target species**

- Intravenous injection of pentobarbital has the ability to cause induction excitement in several species of animal and adequate sedation should be applied if deemed necessary by the veterinary surgeon. Measures should be taken to avoid perivascular administration (e.g. by using intravenous catheter).

- The intraperitoneal route of administration may cause a prolonged onset of action with an increased risk of induction excitement. Intraperitoneal administration must only be used following appropriate sedation. Measures should be taken to avoid administration into the spleen or organs/tissue with low capacity for absorption. This route of administration is only suitable for small animals.

- Intracardiac injection must only be used if the animal is heavily sedated, unconscious, or anesthetized.

To reduce the risk of induction excitement, euthanasia should be performed in a quiet area.

In horses and cattle, premedication with an appropriate sedative must be used to produce profound sedation before euthanasia and an alternative method of euthanasia should be available.

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

- The intravenous route of administration should be the route of choice and adequate sedation should be applied if deemed necessary by the veterinary surgeon. For horses and cattle premedication is mandatory.

Where intravenous administration is impossible, and only following deep sedation, the product may be administered via the intracardiac route in all named species. Alternatively, for small animals only, administration via the intraperitoneal route could be used, following appropriate sedation.

- 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.

- Ingestion of euthanased animals by other animals may lead to intoxication, anaesthesia and even death. Barbiturates are also highly stable to cooking temperature. Due to the risk of secondary intoxication animals euthanased with the veterinary medicinal product should not be fed to other animals but should be disposed of in accordance with national legislation and in a manner that other animals cannot have access to the carcasses.

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

Pentobarbital is a potent hypnotic and a sedative, and thus potentially toxic in man. It can be absorbed systemically through the skin and if swallowed. Particular care should be taken to avoid accidental ingestion and self-injection.

In case of accidental self-injection, ingestion or spillage onto skin or into eyes, seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT drive as sedation may occur.

In case of accidental self-injection, obtain URGENT medical attention, advising medical services of barbiturate poisoning.

In case of spillage onto skin, wash the exposed skin immediately after exposure with large amount of water.

In case of contact with eyes, rinse immediately with plenty of fresh water and obtain medical advice.

In case of ingestion, wash out mouth and obtain medical attention immediately.

Impermeable protective gloves should be worn when handling this product.

People with known hypersensitivity to pentobarbital should avoid contact with the veterinary medicinal product or administer the product with caution.

Advice to Doctor: The concentration of pentobarbital in the product is such that the accidental injection or ingestion of quantities as small as 1ml in human adults can have serious CNS effects. A dose of pentobarbital sodium of 1g (equivalent to 2.5ml of product) has been reported to be fatal in humans. Treatment should be supportive with appropriate intensive therapy and maintaining the respiration.

#### **4.6 Adverse reactions (frequency and seriousness)**

Minor muscle twitching may occur after injection.

Death may be delayed if the injection is administered perivascularly or into organs/tissues with low capacity for absorption. Barbiturates can be irritating when administered perivascularly.

Pentobarbital sodium has the ability to cause induction excitement. Premedication/sedation significantly reduces the risk of experiencing induction excitement.

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**

If euthanasia is necessary, the product can be used in pregnant or lactating animals.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

When an aggressive animal is to undergo euthanasia, premedication with a more easily administered (oral, subcutaneous or intramuscular) sedative is recommended.

Although premedication with sedatives may delay the desired effect of the product due to decreased circulatory function this may not be clinically noticeable since CNS depressant drugs (opioids,  $\alpha_2$  adrenoreceptor agonists, phenothiazines etc) can also increase the effect of pentobarbital.

#### **4.9 Amounts to be administered and administration route**

A dose of 140mg/kg, equivalent to 0.35ml/kg, is considered sufficient for all indicated routes of administration.

The intravenous route of administration should be the route of choice and adequate sedation should be applied if deemed necessary by the veterinary surgeon. For horses and cattle premedication is mandatory.

When intravenous administration is difficult, and only following deep sedation or anaesthesia, the product may be administered via the intracardiac route.

Alternatively, for small animals only, administration via the intraperitoneal route could be used, but only following appropriate sedation.

The intravenous injection in companion animals should be carried out with a continuous injection rate until unconsciousness occurs.

In horses and cattle, pentobarbital should be injected rapidly.

The stopper should not be punctured more than 20 times.

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

Not applicable.

#### **4.11 Withdrawal period(s)**

Adequate measures should be taken to ensure that carcasses of animals treated with this product and the by-products of these animals do not enter the food chain and are not used for human or animal consumption.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: **barbiturates**  
ATCvet code: **QN51AA01**

#### **5.1 Pharmacodynamic properties**

Pentobarbital sodium is an oxybarbiturate derivative of Barbituric Acid. Barbiturates depress the entire central nervous system but, quantitatively, various areas are affected differently making the product a potent hypnotic and sedative. The immediate effect is the unconsciousness of deep anaesthesia followed by, at high dose rates, rapid depression of the respiratory centre. Breathing stops and cessation of heart action quickly follows leading to rapid death.

#### **5.2 Pharmacokinetic particulars**

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.

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 (due to depression of the respiratory centre, the animal may be clinically dead prior cardiac arrest).

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Benzyl alcohol (E1519)

Patent Blue V (E131)

Ethanol (96 per cent)

Propylene glycol

Water for injections

### **6.2 Incompatibilities**

Do not mix with other medicinal products.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 28 days

### **6.4. Special precautions for storage**

Do not freeze.

Store in the original packaging to protect from light.

### **6.5 Nature and composition of immediate packaging**

100 ml colourless type II glass vial with a light grey bromobutyl rubber stopper and an aluminium cap.

250 ml colourless type II glass vial with a dark grey bromobutyl rubber stopper and an aluminium cap.

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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Le Vet B.V.  
Wilgenweg 7  
3421 TV Oudewater  
The Netherlands

**8. MARKETING AUTHORISATION NUMBER**

Vm 19994/4016

**9. DATE OF FIRST AUTHORISATION**

12 December 2011

**10. DATE OF REVISION OF THE TEXT**

December 2011

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Administration only by a veterinary surgeon.  
To be supplied only on veterinary prescription.