Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthasol vet. 400 mg/ml, solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

Active substance:
Pentobarbital sodium 400 mg
(equivalent to pentobarbital 364.6 mg)

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

For the 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 anaesthetised.

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

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 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.

- 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

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. Only carry this product in an unarmed syringe to avoid accidental injection.

Systemic uptake (including absorption via skin or eye) of pentobarbital causes sedation, sleep, CNS and respiratory depression. Moreover, this product may be irritating to the eye and can cause irritation to the skin as well as hypersensitivity reactions (due to the presence of pentobarbital). Embryotoxic effects cannot be excluded.

Avoid direct contact with the skin and eyes, including hand-to-eye contact.
This product is flammable. Keep away from sources of ignition.
Do not smoke, eat or drink while handling the product.

Avoid accidental self-injection or accidental injection of other persons when administering the product.

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

Handle the product with utmost care, especially pregnant and breastfeeding women. Wear protective gloves. This medicine should only be administered by veterinarians and should only be used in the presence of another professional that can assist in case of accidental exposure. Instruct the professional if not a medical professional about the risks of the product.

Accidental spillage on the skin or in the eye must be washed off immediately with plenty of water. If there has been serious skin or eye contact or in the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. In the case of accidental ingestion, wash out mouth and obtain medical attention immediately. But DO NOT DRIVE as sedation may occur.

Information for the health professional in case of exposure:
Emergency measures should be directed toward maintenance of respiration and cardiac function. In severe intoxication measures to enhance elimination of absorbed barbiturate may be necessary.

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

Other precautions
Ingestion of euthanased animals by other animals may lead to intoxication, anaesthesia and even death. Barbiturates are highly persistent in carcasses and also stable to cooking temperature. Due to the risk of secondary intoxication animals euthanised 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 securing that other animals cannot have access to the carcasses.

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

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. Use accordingly to the benefit-risk assessment by the responsible veterinarian.

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, α2 adrenoreceptor agonists, phenothiazines etc) can also increase the effect of pentobarbital.

4.9 Amounts to be administered and administration route

A dose of 140 mg/kg, equivalent to 0.35 ml/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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: **Products for animal euthanasia, barbiturates, pentobarbital**
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 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.

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

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

6.4 Special precautions for storage

Do not freeze.
Keep the container in the outer carton in order 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 products or waste materials

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(S)

VPA 10816/011/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th December 2011

Date of last renewal: 14th October 2016

10 DATE OF REVISION OF THE TEXT

October 2016