Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Repose 500 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Pentobarbital sodium 500 mg
(Equivalent to 455.7 mg pentobarbital)

Excipients
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 aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, cats, rodents, rabbits, cattle, sheep, goats, pigs, 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. In horses, cattle and pigs, premedication with an appropriate sedative is mandatory to produce profound sedation before euthanasia. Measures should be taken to avoid perivascular administration (e.g. by using an intravenous catheter).

In pigs, it was shown that there is a direct correlation between restraint and level of excitation and agitation. Therefore, injection in pigs should be done with the least amount of restraint necessary.
Due to the difficulty of safe intravenous injections in pigs, adequate sedation of the animal before IV administration of pentobarbital is mandatory.

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.

The intracardiac route of administration can only be used in a limited number of species and only if the animal is heavily sedated, unconscious, or anesthetised.

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.

When an aggressive animal is to undergo euthanasia, premedication with a more easily administered (oral, subcutaneous or intramuscular) sedative is recommended.
To reduce the risk of induction excitement, euthanasia should be performed in a quiet area.

An alternative method of euthanasia should be available should it become necessary.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
For use by a veterinary surgeon only.

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.

After administration of this product, collapse will occur within 10 seconds. In case the animal is standing at time of administration, care should be taken by the person administering the veterinary medicinal product and any other persons present to keep a safe distance from the animal to avoid injury.

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 0.8 ml in human adults can have serious CNS effects. A dose of pentobarbital sodium of 1 g (equivalent to 2 ml of product) has been reported to be fatal in humans. Treatment should be supportive with appropriate intensive therapy and maintenance of respiration.

Other precautions
Carcases of animals euthanised with this product should be disposed of in accordance with national legislation. Carcases of animals euthanised with this product should not be fed to other animals due to the risk of secondary intoxication.

4.6 Adverse reactions (frequency and seriousness)

Minor muscle twitching may commonly 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 or subcutaneously.

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

One or a few gasping respirations may uncommonly occur after cardiac arrest. At this stage the animal is already clinically dead.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

If euthanasia is necessary, the product can be used in pregnant or lactating animals.The increased body weight of pregnant animals should be taken into account in the dose calculation. Whenever possible, the product should be injected intravenously. The foetus must not be removed from the maternal body (e.g. for examination purposes) earlier than 25 minutes after confirmation of the death of the mother. In this case, the foetus is to be examined for signs of life and, if necessary, euthanised separately.

4.8 Interaction with other medicinal products and other forms of interactions

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 pentobarbital sodium per kg bodyweight, equivalent to 0.28 ml/kg, is generally considered sufficient for all indicated routes of administration.
In small animals, higher dosages may be applied, especially when using the intraperitoneal route.
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, cattle and pigs premedication is mandatory.
When intravenous administration is difficult, and only following deep sedation or anaesthesia, the product may alternatively be administered via the intracardiac route in all species except cattle and horses.
Alternatively, for small animals only, administration via the intraperitoneal route could be used, but only following appropriate sedation.

The different administration methods for each animal species must be followed carefully (see schedule).

Horses, cattle

Rapid intravenous injection	Premedication is mandatory

Pigs

-The route of administration depends on the age and weight of the individual and can be intravenous vena cava cranialis or ear vein. -Intracardiac route	Premedication is mandatory

Sheep, goat

-Rapid intravenous injection -Intracardiac route	When using the intracardiac route, premedication is mandatory.

Dog, cat

-Intravenous injection with a continuous injection rate until unconsciousness occurs. -Intracardiac route -Intraperitoneal route	When using the intracardiac or intraperitoneal route, premedication is mandatory.

Rabbits, rodents, mink

-Intravenous route -Intracardiac route -Intraperitoneal route	When using the intracardiac or intraperitoneal route, premedication is mandatory.

The stopper should not be punctured more than 40 times using a 21G needle.
The stopper should not be punctured more than 10 times using a 18G needle.
Consequently the user should choose the most appropriate vial size.

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: 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96 per cent)
Patent blue V (E131)
Hydrochloric acid, dilute (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after opening of the immediate packaging: 56 days

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Clear Type I glass vials containing 100 ml or 250 ml, and polypropylene vials containing 100 ml or 250 ml closed with a bromobutyl rubber stopper and aluminium cap in a carton box.
Carton box pack sizes:
1 or 12 vials of 100 ml.
1 or 12 vials of 250 ml.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10475/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th May 2017

10 DATE OF REVISION OF THE TEXT

May 2020