1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Repose 500 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent blue V (E131)	0.01 mg
Ethanol (96 per cent)	
Hydrochloric acid, dilute (for pH adjustment)	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Clear, blue aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats, rodents, rabbits, cattle, sheep, goats, pigs, horses and minks.

3.2 Indications for use for each target species

Euthanasia.

3.3 Contraindications

Do not use for anaesthesia.

3.4 Special warnings

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.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

In horses and cattle, 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 which is toxic in humans. It can be absorbed systemically through the skin or eye and if swallowed. Systemic uptake (including absorption via skin or eye) of pentobarbital causes sedation, sleep, CNS and respiratory depression. Particular care should be taken to avoid accidental ingestion and self-injection. Only carry this veterinary medicinal product in an unarmed syringe to avoid accidental injection.

In the case of accidental ingestion, wash out mouth and obtain medical attention immediately.
Accidental spillage on the skin or in the eye must be washed off immediately with plenty of water.
Avoid accidental self-injection or accidental injection of other persons when administering the veterinary medicinal product.
In case of accidental self-injection or serious skin and/or eye contact, seek medical advice immediately and show the package leaflet or the label to the physician. But DO NOT DRIVE as sedation may occur.

Embryotoxic effects cannot be excluded.
Pregnant and breastfeeding women must take extra precautions when handling this veterinary medicinal product.
This veterinary medicinal 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). People with known hypersensitivity to pentobarbital should avoid contact with the veterinary medicinal product.

Avoid direct contact with the skin and eyes, including hand-to-eye contact.
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 veterinary medicinal product.
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
Do not smoke, eat or drink while handling the veterinary medicinal product.

After administration of this veterinary medicinal 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.
This veterinary medicinal product is flammable. Keep away from sources of ignition.

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 veterinary medicinal 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 ml of veterinary medicinal product) has been reported to be fatal in humans. Treatment should be supportive with appropriate intensive therapy and maintenance of respiration.

Special precautions for the protection of the environment:

Not applicable.

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

3.6 Adverse events

Dogs, cats, rodents, rabbits, cattle, sheep, goats, pigs, horses and minks:

Common (1 to 10 animals / 100 animals treated):	Twitching[a]
Uncommon (1 to 10 animals / 1,000 animals treated):	Agonal breathing[b]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Excitation[c]

[a] Minor.
[b] May occur after cardiac arrest. At this stage the animal is already clinically dead.
[c] Premedication/sedation significantly reduces the risk of experiencing induction excitement.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
If euthanasia is necessary, the veterinary medicinal 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 veterinary medicinal 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.

3.8 Interaction with other medicinal products and other forms of interaction

Although premedication with sedatives may delay the desired effect of the veterinary medicinal 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.

3.9 Administration routes and dosage

Intravenous, intracardiac or intraperitoneal use.

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 use is difficult, and only following deep sedation or anaesthesia, the veterinary medicinal product may alternatively be administered via the intracardiac route in all species except cattle and horses.
Alternatively, for small animals only - rodents, rabbits, mink and dogs and cats with a small patient size, such as puppies and kittens, 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 use	Premedication is mandatory.

Pigs

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

Sheep, goats

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

Dogs, cats

- Intravenous injection with a continuous injection rate until unconsciousness occurs - Intracardiac use - Intraperitoneal use (small patient size only)	When using the intracardiac or intraperitoneal route, premedication is mandatory.

Rabbits, rodents, minks

- Intravenous use - Intracardiac use - Intraperitoneal use	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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN51AA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 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.

Pack sizes:
Carton box containing 1 or 12 vials of 100 ml.
Carton box containing 1 or 12 vials of 250 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/030/001

8. DATE OF FIRST AUTHORISATION

05 May 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

09 December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).