

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Repose 500 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Pentobarbital 455.7 mg
(equivalent to 500 mg pentobarbital sodium)

3. PACKAGE SIZE

100 ml
250 ml
12 x 100 ml
12 x 250 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use, intracardiac use, intraperitoneal use.

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 56 days.

Once broached use by...

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 41821/4042

15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {100 ml and 250 ml
glass vial, 100 and 250 ml polypropylene vial}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Repose 500 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Pentobarbital 455.7 mg
(equivalent to 500 mg pentobarbital sodium)

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Intravenous use, intracardiac use, intraperitoneal use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 56 days.
Once broached use by...

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Repose 500 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance

Pentobarbital 455.7 mg
(equivalent to 500 mg pentobarbital sodium)

Excipients:

Patent blue V (E131) 0.01 mg

Clear, blue aqueous solution.

3. Target species

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

4. Indications for use

Euthanasia.

5. Contraindications

Do not use for anaesthesia.

6. Special warnings

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 anaesthetised.

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 unarmoured 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.

Other precautions:

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

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.

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, α_2 adrenoreceptor agonists, phenothiazines etc.) can also increase the effect of pentobarbital.

Major incompatibilities:

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

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.
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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.
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Sheep, goats

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

- Intravenous use - Intracardiac use - Intraperitoneal use	When using the intracardiac or intraperitoneal route, premedication is mandatory.
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To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

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.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging : 56 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41821/4042

Pack sizes: 1 or 12 vials of 100 ml, 1 or 12 vials of 250 ml.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Approved 05 February 2025
Gavin Hall