[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Repose 500 mg/ml solution for injection (AT, BE, BG, CY, CZ, EL, ES, HR, HU, IE, IT, LU, MT, PT, RO, SI, SK, UK)
Repose vet 500 mg/ml solution for injection (DK, FI, IS, NO, SE, EE, LT, LV, PL)
Repose solution for injection (FR)
Euthasol 500 mg/ml solution for injection (NL)

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 minks.

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.

Intracardiac injection must only be used 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.

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 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 product. In the 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 product.
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). 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 product.
Wear impervious gloves when handling the product.
Do not smoke, eat or drink while handling the product.

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.

This 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 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 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 and lactation

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 interaction

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 - 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 injection	Premedication is mandatory.

Pigs

- Rapid intravenous injection - 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, goats

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

Dogs, cats

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

Rabbits, rodents, minks

- 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 PROPERTIES

Pharmacotherapeutic group: 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 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.
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.

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY
Date of last renewal: DD/MM/YYYY

10. DATE OF REVISION OF THE TEXT

MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Repose 500 mg/ml solution for injection
pentobarbital sodium

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Pentobarbital sodium 500 mg equivalent to pentobarbital 455.7 mg

3. PHARMACEUTICAL FORM

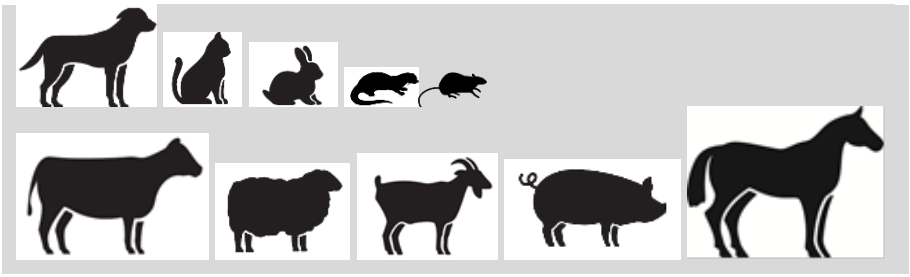
Solution for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

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



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

For full user warnings and disposal instructions, see package leaflet.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 56 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. For use by a veterinary surgeon only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S 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
pentobarbital sodium

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Pentobarbital sodium 500 mg equivalent to pentobarbital 455.7 mg

3. PHARMACEUTICAL FORM

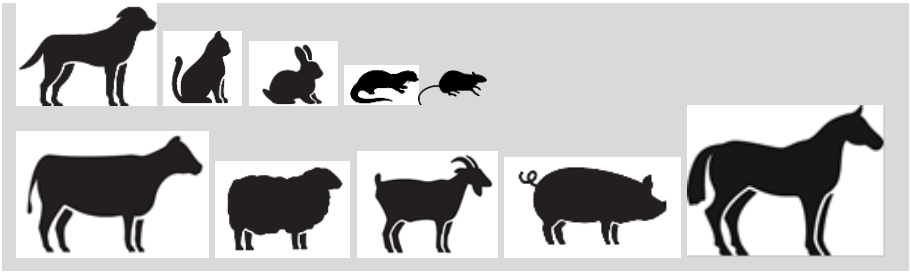
Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

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



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

For full user warnings and disposal instructions, see package leaflet.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 56 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. For use by a veterinary surgeon only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Repose 500 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Repose 500 mg/ml solution for injection
pentobarbital sodium

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml contains:
Active substance
Pentobarbital sodium 500 mg equivalent to 455.7 mg pentobarbital
Excipients
Patent blue V (E131) 0.01 mg

Clear, blue aqueous solution.

4. INDICATION(S)

Euthanasia.

5. CONTRAINDICATIONS

Do not use for anaesthesia.

6. ADVERSE REACTIONS

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.

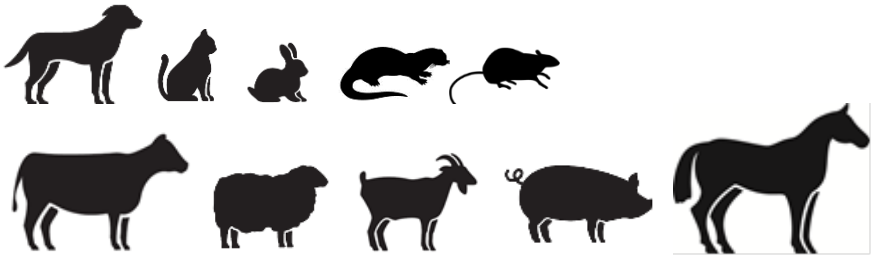
One or a few gasping respirations may uncommonly occur after cardiac arrest. At this stage the animal is already clinically dead.

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).

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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

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



8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 - 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 injection	Premedication is mandatory.

Pigs

- Rapid intravenous injection	Premedication is mandatory.

- 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	

Sheep, goats

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

Dogs, cats

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

Rabbits, rodents, minks

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

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 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.

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 container: 56 days.

12. SPECIAL WARNING(S)

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.

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

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.

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 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 product. In the 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 product.
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). 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 product.
Wear impervious gloves when handling the product.
Do not smoke, eat or drink while handling the product.

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.
This 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 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 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

Pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction:
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.

Overdose (symptoms, emergency procedures, antidotes):
Not applicable.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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