1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthasol vet. 400 mg/ml, solution for injection (AT, BE, DK, EE, EL, FI, IE, IS, LT, LU, LV, NO, PL, PT, RO, SE, UK (NI))
Euthasol 400 mg/ml, solution for injection (ES, IT)
Euthasol vet. solution for injection (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Pentobarbital 364.6 mg
(equivalent to 400 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**
Benzyl alcohol (E1519)	20 mg
Patent Blue V (E131)	0.01 mg
Ethanol (96 per cent)	
Propylene glycol	
Water for injections	

Clear blue liquid.

3. CLINICAL INFORMATION

3.1 Target species

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

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. 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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 veterinary medicinal 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 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). Embryotoxic effects cannot be excluded.

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

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

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

Handle the veterinary medicinal product with utmost care, especially pregnant and breastfeeding women. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product. 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.

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 seek medical advice immediately and show the package leaflet or the label to the physician. 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 veterinary medicinal product is such that the accidental injection or ingestion of quantities as small as 1ml in human adults can have serious CNS effects. A dose of pentobarbital sodium of 1 g (equivalent to 2.5 ml of veterinary medicinal product) has been reported to be fatal in humans. Treatment should be supportive with appropriate intensive therapy and maintaining the respiration.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:
Ingestion of euthanised 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.

3.6 Adverse events

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

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Twitching[a] Agonal breathing[b] 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.

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

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 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 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/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 veterinary medicinal 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.

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

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 veterinary medicinal 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 (due to depression of the respiratory centre, the animal may be clinically dead prior cardiac arrest).

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

5.3 Special precautions for storage

Do not freeze.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

100 ml colourless type I glass vial with a light grey bromobutyl rubber stopper and an aluminium cap.
250 ml colourless type I glass vial with a dark grey bromobutyl rubber stopper and an aluminium cap.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthasol vet. 400 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Pentobarbital 364.6 mg
(equivalent to 400 mg pentobarbital sodium)

3. PACKAGE SIZE

100 ml
250 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous, intracardiac or intraperitoneal use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Carcasses of animals treated with this veterinary medicinal product and by products of these animals should not enter the food chain.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Keep the vial in the outer carton in order to protect from light.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthasol vet. 400 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Pentobarbital 364.6 mg
(equivalent to 400 mg pentobarbital sodium)

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

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

5. WITHDRAWAL PERIODS

Withdrawal periods: read the package leaflet before use.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Euthasol vet. 400 mg/ml, solution for injection

2. Composition

Each ml contains:

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

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

Clear blue liquid.

3. Target species

Dogs, cats, rodents, rabbits, cattle, sheep, goats, 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. 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.

Special precautions for safe use in the target species:
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 veterinary medicinal 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.

Systemic uptake (including absorption via skin or eye) of pentobarbital causes sedation, sleep, CNS and respiratory depression. Moreover, 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). Embryotoxic effects cannot be excluded.

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

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

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

Handle the veterinary medicinal product with utmost care, especially pregnant and breastfeeding women. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product. 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.

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 seek medical advice immediately and show the package leaflet or the label to the physician. 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 veterinary medicinal product is such that the accidental injection or ingestion of quantities as small as 1ml in human adults can have serious CNS effects. A dose of pentobarbital sodium of 1 g (equivalent to 2.5 ml of veterinary medicinal 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 euthanised 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 euthanased 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

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 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.

Special restrictions for use and special conditions for use:

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, horses and minks:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Twitching[a] Agonal breathing[b] 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.

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Intravenous, intracardiac or intraperitoneal use.

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 anesthesia, the veterinary medicinal 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.

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

9. Advice on correct administration

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.

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.

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.

Do not freeze.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.
The stopper should not be punctured more than 20 times.

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

Pack sizes:
100 ml
250 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

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 events:

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

17. Other information