1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthatal 500 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Pentobarbital sodium 500 mg
(equivalent to 456 mg pentobarbital)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (96 per cent)	
Patent blue V (E131)	0.001 mg
Water for injection	

Pale blue transparent solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, goats, sheep, dogs, cats, rabbits, guinea pigs, mice, rats, hamsters, chickens, pigeons, ducks, small ornamental birds, snakes, turtles, lizards and frogs.

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 must be taken to avoid perivascular administration (e.g. by using intravenous catheter). Death may be delayed if the injection is administered perivascular, intraperitoneal/intracoelomic or into organs/tissues with low capacity for absorption. Barbiturates can be irritating when administered perivascular or by other routes than intravenous administration.

Check regularly, up to about 10 minutes post-administration, if live signs return (respiration, heartbeat, corneal reflex). In clinical trials it has been established that this might occur. If such live signs return, it is advised to repeat the administration using between 0.5 and 1 times the prescribed dose. To reduce the risk of induction excitement, euthanasia should be performed in a quiet area.

In pigs, it was shown that there is a direct correlation between restraint and level of excitation and

agitation. Therefore, injection in swine should be done with the least amount of restraint necessary.

Particularly in horses and cattle, the veterinary surgeon should consider premedication with an appropriate sedative to produce profound sedation before euthanasia and an alternative method of euthanasia is recommended to be available should it become necessary.
If the intracoelomic route is used for birds, injection into the air sacs must be avoided.
The intracoelomic route is not advised in turtles, as the time to death may be prolonged.
In reptiles and amphibians, appropriate measures (e.g. pithing) should be taken to ensure that euthanasia is complete, as their brains can survive prolonged anoxia and recovery following metabolism of pentobarbital may occur otherwise.
When euthanasia of poikilotherms is undertaken, the animal must be maintained at its preferred optimum temperature, otherwise efficacy may be unreliable.

3.5 Special precautions for use

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. Pentobarbital causes sedation, sleep induction and respiratory depression. It can be adsorbed systemically through the skin and if swallowed. Moreover, this veterinary medicinal product may be irritating to the eye.

Avoid direct contact with the skin and eyes, including hand-to-eye and hand-to-mouth contact. Wear protective gloves.

Particular care should be taken to avoid self-injection or accidental injection of a second professional when administering the veterinary medicinal product. Only carry this veterinary medicinal product in an unarmed syringe to avoid accidental self-injection.

Accidental spillage on the skin or in the eye must be washed off immediately with plenty of water. In case of accidental ingestion, wash out mouth immediately.

If there has been serious skin or eye contact or in case of accidental ingestion or self-injection, seek medical attention immediately, indicate poisoning with barbiturates and show the package leaflet or the label to the physician. DO NOT DRIVE as sedation may occur.

Embryotoxic effects cannot be excluded. Handle the veterinary medicinal product with utmost care, especially women of childbearing potential.

This veterinary medicinal product may cause hypersensitivity reactions due to the presence of pentobarbital. People with known hypersensitivity to pentobarbital should avoid contact with the veterinary medicinal product.

This veterinary medicinal product is flammable, keep away from sources of ignition. Do not smoke.

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.

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 certain 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. Do not leave the patient unattended.

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:
Carcasses and edible products of animals injected with this veterinary medicinal product may never enter the food chain (see section 3.12) and should be disposed of in accordance with national legislation.
Carcasses or parts of the carcass of animals euthanised with this veterinary medicinal product should not be fed to other animals due to the risk of secondary intoxication (see section 3.12).

3.6 Adverse events

All target species:

Common (1 to 10 animals / 100 animals treated):	Vocalisation Twitching
Rare (1 to 10 animals / 10,000 animals treated):	Excitation Involuntary movement (leg) Involuntary defecation Involuntary urination
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Convulsion Hiccup Vomiting Agonal breathing (gasping)[1]
Undetermined frequency (cannot be estimated from the available data)	Immediate pain on injection[2]

[1] One or few gasping respirations occur after cardiac arrest.
[2] Barbiturates can be irritating when administered by other routes than intravenous administration.

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Agonal breathing (gasping)[1]

[1] mostly due to underdosing

Birds:

Very common (>1 animal / 10 animals treated):	Tonic muscle spasm Feather erection

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:
No specific information is available.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

CNS depressants (narcotics, phenothiazines, antihistamines, etc.) may increase the effect of pentobarbital.

3.9 Administration routes and dosage

Intravenous use.
Intraperitoneal/intracoelomic use.
Intracardiac use.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The veterinary medicinal product is preferably administered through a single fast intravenous injection.
For larger animals, the use of a pre-inserted intravenous catheter is advocated.

When administering the veterinary medicinal product by a route other than intravenously the animals must be heavily sedated or unconscious and not show any reaction to pain stimuli, except for intraperitoneal administration to rats and mice. Intracardiac injection is only acceptable after prior deep sedation or anaesthesia.

The use of pentobarbital intraperitoneally in non-sedated rats and mice is only acceptable when measures to avoid mis-injection have been taken, including the use of appropriate needle sizes (e.g., 26G for mice).

For the intraperitoneal or intracoelomic routes of administration, higher doses are recommended when feasible.

If cardiac arrest is not established after 2 minutes, a second dose needs to be administered, preferably via fast intravenous injection or if applicable, via intra-cardiac injection.

The following table contains the dosage information for each animal species:

Target animal species	Route of administration	Dose
Cattle, horses, pigs, goats, sheep, cats, dogs	Intravenous	The recommended dose is 100 mg/kg b.w. (corresponding to 0.2 ml/kg).
Mice	Intravenous Intraperitoneal Intracardiac	The minimum dose is 250 mg/kg b.w. (corresponding to 0.5 ml/kg), up to 1600 mg/kg b.w. can be used.
Rats	Intravenous Intraperitoneal Intracardiac	The minimum dose is 200 mg/kg b.w. (corresponding to 0.4 ml/kg), up to 800 mg/kg b.w. can be used.
Rabbits, hamsters, guinea pigs	Intravenous Intraperitoneal Intracardiac	The recommended dose is 200 mg/kg b.w. (corresponding to 0.4 ml/kg).
Chicken, pigeons, ducks,	Intravenous Intracoelomic Intracardiac	The recommended dose is 200 mg/kg b.w. (corresponding to 0.4 ml/kg).
Small ornamental birds	Intracoelomic	The recommended dose is 1300 mg/kg (corresponding to 2.6 ml/kg)

Snakes	(Intravenous) Intracoelomic Intracardiac	The recommended dose is 200 mg/kg b.w. (corresponding to 0.4 ml/kg). Intracoelomic or intracardiac administration should be the first choice.
Turtles	Intravenous Intracoelomic Intracardiac	The minimum dose is 200 mg/kg b.w. (corresponding to 0.4 ml/kg), for intracoelomic administration doses up to 1100 mg/kg b.w. can be used.
Lizards	Intravenous Intracoelomic Intracardiac	The minimum dose is 400 mg/kg b.w. (corresponding to 0.8 ml/kg), doses up to 800 mg/kg b.w. can be used.
Frogs	(Intravenous) Intracoelomic Intracardiac	The minimum dose is 200 mg/kg b.w. (corresponding to 0.4 ml/kg), doses up to 1100 mg/kg b.w. can be used. Intracoelomic or intracardiac administration should be the first choice.

For ease of administration the veterinary medicinal product could be diluted with isotonic (0.9%) sodium chloride solution in a mixing ration of 1:1 prior to administration when using thin needles. The stopper should not be punctured more than 20 times.

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

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.
In view of the activity of this veterinary medicinal product, double dosage is discouraged, as this will not result in a faster or better euthanasia.

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

Appropriate measures need to be taken to assure that carcasses and edible products of animals injected with this veterinary medicinal product do not enter the food chain, and are not used for human consumption. Other animals may never eat (parts of) the carcass, as they might be exposed to a lethal dose of pentobarbital.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN51AA01

4.2 Pharmacodynamics

Pentobarbital is a short-acting sedative and hypnotic. It causes depression of the central nervous system by GABA receptor modulation, imitating the action of Gamma-aminobutyric acid. Barbiturates suppress in particular the reticular activating system (RAS) in the brain, which normally ensures alertness. The immediate effect is the loss of consciousness followed by deep anaesthesia followed by, at high rates, rapid depression of the respiratory centre. Breathing stops and is quickly followed by cardiac arrest and rapid death.

4.3 Pharmacokinetics

After intravenous administration fast distribution over the tissues will occur. Fast, but slower than intravenous administration distribution will occur after intraperitoneal or intracoelomic administration. Pentobarbital is mainly eliminated through the liver by biotransformation, particularly by the Cytochrome P_{450} system, as well as by excretion in the kidneys and redistribution. In pigs redistribution in fatty tissue might cause reduced plasma concentrations and prolonged action. Barbiturates may diffuse through the placenta in foetal tissue.

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, except sterile, isotonic sodium chloride (0.9%) solution.

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: 63 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

1 bottle of 100 ml, type I glass with bromobutyl rubber stopper and aluminium cap in a carton box

Pack sizes:
1 x 100 ml
12 x 100 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

This veterinary medicinal product is dangerous to humans and animals.
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

WDT - Wirtschaftsgenossenschaft deutscher Tierarzte eG

7. MARKETING AUTHORISATION NUMBER(S)

VPA10660/006/001

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).