1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthoxin 500 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each ml contains:

Pentobarbital 455.7mg
(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**
Erythrosine red (E127)	0.05 mg
Propylene glycol	-
Water for injections	-

Clear, pink solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chickens, pigeons, ornamental birds, small snakes, tortoises, lizards, frogs, horses, cattle, pigs.

3.2 Indications for use for each target species

Euthanasia.

3.3 Contraindications

Do not use for anaesthetic purposes.
Do not use for intracoelomic injection in chelonia as the time to death may be unnecessarily prolonged compared with intravenous administration.

3.4 Special warnings

To reduce the risk of CNS excitement, it is recommended to perform euthanasia 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. In individual cases – especially in restrained animals – agitation/excitation could occur during administration resulting in accidental paravenous administration of the product. Due to the difficulty of safe intravenous injections in swine adequate sedation of the animal before IV administration of pentobarbital is recommended. Application via marginal ear vein should at least initially be performed

without fixation. The animals should be restrained between the legs of an assisting person. If fixation is necessary, a snout rope should be used.

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 should it become necessary.

When euthanasia of **poikilotherms** is undertaken, the animal must be maintained at its preferred optimum temperature, otherwise efficacy may be unreliable. Species appropriate measures (e.g., pithing) should be taken to ensure that euthanasia is complete, and that spontaneous recovery does not occur.

Venomous snakes are best euthanized by injecting pentobarbital solution into the body cavity near the heart, with judicious use of prior sedation in order to minimise danger to humans.

Intravenous injection of pentobarbital has the ability to cause CNS excitement in several species of animal and adequate sedation should be administered if deemed necessary by the veterinary surgeon. Measures must be taken to avoid perivascular administration (e.g. by using an intravenous catheter).

The **intraperitoneal** route of administration may cause a prolonged onset of action with an increased risk of CNS excitement. Intraperitoneal administration must only be used following appropriate sedation. Measures must 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 mammals.

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

The **intrapulmonary** route of administration may cause a prolonged onset of action with an increased risk of adverse effects noted in 3.6 and must be reserved for cases where other routes of administration are not possible. Intrapulmonary administration may only be used in chickens, pigeons, ornamental birds, snakes, tortoises, lizards and frogs. Animals must be heavily sedated, unconscious or anaesthetized before this route of administration is employed. Do not use intrapulmonary administration in any other target animal species.

Check regularly, up to about 10 minutes post-administration, in case signs of life return (respiration, heartbeat, corneal reflex). In clinical trials it has been established that signs of life may return. If this occurs, it is advised to repeat the administration using between 0.5 and 1 times the recommended dose.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product does not contain any antimicrobial preservative.

When an aggressive animal is to undergo euthanasia, premedication with a more easily administered (oral, subcutaneous or intramuscular) sedative is recommended.
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.

Pigs and small animals: See also section 3.9 for recommendations regarding dilution of product.

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 drug which is toxic in humans – particular care must 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 induction, and CNS and respiratory depression.
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.

Avoid direct contact with the skin and eyes, including hand-to-eye contact.
Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product – pentobarbital can be absorbed via skin and mucosa.

Moreover, 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 and benzyl alcohol). People with known hypersensitivity to pentobarbital or to any other ingredient should avoid contact with the veterinary medicinal product.

This product should only be used in the presence of another person that can assist in case of accidental exposure. Instruct that person if not a medical professional about the risks of 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.

In the event of accidental exposure the following action should be taken:

Skin – Wash immediately with water and then thoroughly with soap and water. Seek medical advice immediately and show the package leaflet or the label to the physician.

Eyes – Rinse immediately with plenty of cold water. Seek medical advice immediately and show the package leaflet or the label to the physician.

Ingestion –Wash out mouth. Seek medical advice immediately and show the package leaflet or the label to the physician. Keep warm and rest.

Accidental self-injection – Obtain URGENT medical attention (take the package leaflet with you), advising medical services of barbiturate poisoning. Do not leave the animal unattended.

DO NOT DRIVE as sedation may occur.

This product is flammable. Keep away from sources of ignition. Do not smoke.

To the physician: Urgent care should be taken to maintain airways and cardiac function. In case of severe intoxication, additional measures should be taken to enhance the elimination of the barbiturate. Give symptomatic and supportive treatment.

Information for the health professional in case of exposure:
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 1g (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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Due to the risk of secondary intoxication animals euthanized 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, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chickens, pigeons, ornamental birds, small snakes, tortoises, lizards, frogs, horses, cattle, pigs:

Common (1 to 10 animals / 100 animals treated)	Vocalisation, Twitching [1]
Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)	Agonal breathing[2,3]
Rare (1 to 10 animals / 10,000 animals treated)	Excitation Involuntary movement Involuntary defecation Involuntary urination Agonal breathing [4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Convulsion Hiccup Vomiting Agitation [5]
Undetermined frequency (cannot be estimated from the available data	Respiratory distress[2] Coughing[2] Application site irritation[6]

[1] Minor muscle twitching may occur after injection.
[2] After administration via the intra-pulmonary route, symptoms may include shortness of breath.
[3] One or a few gasps following cardiac arrest.
[4] In cattle, this may occur rarely if pentobarbital is administered at a dose lower than the recommended amount.
[5] Transient
[6] Barbiturates can cause irritation when administered subcutaneously or perivascularly

Death may be delayed if the injection is administered perivascularly or into organs/tissues with low capacity for absorption.

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 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, euthanized separately.

3.8 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.

3.9 Administration routes and dosage

Depending on species and circumstances this product may be administered via several routes.
The applicable dose depends on animal species and route of administration. Therefore, the instructions described in the dosage scheme should be carefully followed:

Intravenous route
The intravenous route of administration should be the route of choice and adequate sedation should be administered if deemed necessary by the attending veterinarian. For horses and cattle premedication is mandatory.

Intracardiac route
Where intravenous administration is difficult and only following deep sedation or anaesthesia, the product may be administered via the intracardiac route in all target species except avian species.

Intraperitoneal route
Alternatively, for small animals only, administration via the intraperitoneal route could be used, but only following appropriate sedation.

Intrapulmonary route
Intrapulmonary administration must only be used as a **last resort** and only if the animal is heavily sedated, unconscious or anaesthetised and shows no response to noxious stimuli. This route of administration may only be used in chickens, pigeons, ornamental birds, snakes, tortoises, lizards and frogs.

Recommendations for dilution of product
Pigs (in case of administration in ear vein) and small animals (dogs, cats, mink, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chickens, pigeons, ornamental birds): For ease of administration the product should be diluted with isotonic (0.9%) sodium chloride solution in a mixing ration of 1:1 prior to administration with needles thinner than 20G.

Target species	Route	Dose expressed as ml of the product	Dose expressed as mg pentobarbital sodium
Horses The product should be injected as quickly as possible. Premedication before administration is mandatory.	Intravenous (rapid injection)	1.0 ml per 5 kg	100 mg per kg
Cattle The product should be injected as quickly as possible. In cattle, in particular at lower dosages, it is possible to observe gasping in isolated cases. Premedication before	Intravenous (rapid injection)	1 - 2 ml per 10 kg	50mg to 100 mg per kg

administration is mandatory.			
Pigs The product should be injected as quickly as possible. The route of administration depends on the age and weight of the individual and can be intravenous (vena cava cranialis or ear vein) or intracardiac. The injection duration can - depending on the age and body weight of the pig –vary from 1 second (piglets) and 38 seconds (in boars> 100 kg body weight).	Intravenous (vena cava cranialis) by rapid injection Intravenous (ear vein) by rapid injection after dilution with isotonic (0.9%) NaCl solution at a ratio of 1:1 Intracardiac (in unconscious or deeply sedated/anaesthetised animals)	0.16 ml per kg up to 30 kg 0.08 ml per kg over 30 kg 0.16 ml per kg up to 30 kg 0.08 ml per kg over 30 kg 0.16 ml per kg up to 30 kg 0.08 ml per kg over 30 kg	80 mg per kg up to 30kg 40 mg per kg over 30kg 80 mg per kg up to 30kg 40 mg per kg over 30kg 80 mg per kg up to 30kg 40 mg per kg over 30kg
Dogs&Cats	Intravenous; slow continuous injection until unconscious then rapid injection of remaining quantity Intracardiac &intraperitoneal: in unconscious or deeply sedated/anaesthetised animals	1.0 ml per 4 kg Dog 1.0 ml per 3 kg Cat 1.0 ml per 3 kg Dog 1.0 ml per 2 kg Cat	125 mg per kg Dog 166 mg per kg Cat 166 mg per kg Dog 250 mg per kg Cat
Mink, polecats	Intravenous Intracardiac (in unconscious or deeply sedated/anaesthetised animals)	1.0 ml per animal	500 mg per animal
Hares, rabbits, guinea pigs, hamsters, rats, mice	Intravenous Intracardiac (in unconscious or deeply sedated/anaesthetised animals) Intraperitoneal (in unconscious or deeply sedated/anaesthetised animals)	1.0 ml per 1.5 kg 1.0 ml per 1kg	333 mg per kg 500 mg per kg
Chickens, pigeons, ornamental birds The method of choice in birds is intravenous injection. If venepuncture cannot be performed (due to e.g. haematoma, collapse of	Intravenous & Intrapulmonary (in unconscious or deeply sedated/anaesthetised animals)	1.0 ml per 1 kg	500 mg per kg

cardiovascular system) intrapulmonary injection could be an option. In birds, intrapulmonary injection is performed by inserting the cannula in a dorso-ventral direction on the left or right side of the backbone into the lung (3rd or 4th intercostal segment between backbone and scapula).			
Small snakes, tortoises, lizards, frogs	Depending on the size, inject into the body cavity near the heart; death is expected after about 5 to 10 minutes in unconscious or deeply sedated/anaesthetised animals	0.4 – 0.8 ml per animal	200 to 400 mg per animal

The stopper should not be punctured more than 50 times.

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

Do not use in animals intended for human or animal consumption.
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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QN51AA01

4.2 Pharmacodynamics

Pentobarbital is a narcotic belonging to the group of barbituric acid derivatives. The LD50 in dogs and cats is approximately 40 to 60 mg/kg bodyweight when injected intravenously. However, for euthanasia of animals highly excessive doses are administered. In endothermic animals, the immediate effect is the

loss of consciousness followed by deep anaesthesia followed by death. Breathing stops and is quickly followed by cardiac arrest. In poikilothermic animals death may be delayed depending upon the rate of absorption and metabolism of the product.

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 to cardiac arrest).

4.3 Pharmacokinetics

The distribution of pentobarbital in the organism is quite even. The highest concentrations were found in the liver. In adipose tissue no accumulation could be shown. Pentobarbital passes the placental barrier and also enters milk. The elimination half-life has been reported to be approximately 1 hour in small ruminants, 2 to 7.5 hours in cats and 7 to 12.5 hours in dogs.

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: 4 years.
Shelf-life after first opening the immediate packaging: 28 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

100 ml Type I amber multi-dose glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium overseal. The product is presented in a carton box.

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.

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

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/115/001

8. DATE OF FIRST AUTHORISATION

15/04/2016

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

16/04/2025

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).