

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthanimal 20%, 200 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:

Sodium pentobarbital 200 mg (equivalent to 182 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
Benzyl alcohol (E 1519)	20.0 mg
Ethanol 96%	80.0 mg
Ponceau 4R (E 124)	0.02 mg
Propylene glycol	
Water for injections	

Clear, red solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs, goats, sheep, cattle, horses, cats and dogs.

3.2 Indications for use for each target species

For 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

perivascularly or into organs/tissues with low capacity for absorption. Barbiturates can be irritating when administered perivascularly.

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.

Avoid use in animals weighing more than 120 kg due to the large injection volume required and difficulty achieving rapid administration.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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).

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 adsorbed 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 induction 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 and benzyl alcohol). Embryotoxic effects cannot be excluded.

Avoid direct contact with the skin and eyes, including hand-to-eye contact.
Do not eat or drink while handling the veterinary medicinal product.

Avoid accidental self-injection or accidental injection of a second professional when administering the veterinary medicinal product. Only carry this veterinary medicinal product in an unarmoured syringe to avoid accidental self-injection.

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

Handle the veterinary medicinal product with utmost care, especially women of childbearing potential. Wear protective gloves. 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. 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.

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.

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

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 5 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.

3.6 Adverse events

Pigs, goats, sheep, cattle, horses, cats and dogs:

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 Agonal breathing (gaspings) ¹

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Convulsion Hiccup Vomiting Agonal breathing (gaspings) ²
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¹ In cattle, mostly due to underdosing.

² One or few gasping respirations occur after cardiac arrest.

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.

Cattle, horses, pigs, goats, sheep, cats and dogs: 100 mg/kg (corresponding to 0.5 ml/kg) through quick intravenous injection. For larger animals, the use of a pre-inserted intravenous catheter is advocated.

If cardiac arrest is not established after 2 minutes, a second dose needs to be administered, preferably via fast intravenous injection or if this is not feasible, via intra-cardiac injection; intra-cardiac injection is only acceptable after prior deep sedation or anaesthesia.

As the vial cannot be punctured more than 20 times, the user should choose the most appropriate vial size.

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

3.12 Withdrawal periods

Not applicable.

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. Pentobarbital is mainly eliminated through the liver by biotransformation, particularly by the Cytochrome P₄₅₀ 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, and traces of barbiturates may be present in the breast milk.

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

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

1 vial of 100 ml or 1 vial of 250 ml, type II glass injection vial with a bromobutylrubber stopper and aluminium cap in carton box.

12 vials of 100 ml or 6 vials of 250 ml, type II glass injection vial with a bromobutylrubber stopper and aluminium cap in polystyrene box.

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

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 36408/3050

8. DATE OF FIRST AUTHORISATION

02 October 2013

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

October 2024

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) (<https://medicines.health.europa.eu/veterinary>).

Gavin Hall

Approved 10 October 2024