

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton box or polystyrene package**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Euthanimal 20%, 200 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains

**Active substance:**

Sodium pentobarbital 200 mg (equivalent to 182 mg pentobarbital)

**3. PACKAGE SIZE**

1 x 100 ml  
1 x 250 ml  
12 x 100 ml  
6 x 250 ml

**4. TARGET SPECIES**

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

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Intravenous use.

**7. WITHDRAWAL PERIODS**

Withdrawal period:  
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.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

**9. SPECIAL STORAGE PRECAUTIONS**

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

Do not use for anaesthesia.

Accidental injection is dangerous.

**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**

Alfasan Nederland B.V.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 36408/3050

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Glass vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Euthanimal 20%, 200 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains

**Active substance:**

Sodium pentobarbital 200 mg (equivalent to 182 mg pentobarbital)

**3. TARGET SPECIES**

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

**4. ROUTES OF ADMINISTRATION**

Intravenous use.

**5. WITHDRAWAL PERIODS**

Withdrawal period:

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.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached, use by \_\_ . \_\_ . \_\_\_\_

**7. SPECIAL STORAGE PRECAUTIONS**

Keep the vial in the outer carton.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Alfasan Nederland B.V.

**9. BATCH NUMBER**

Lot {number}

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET**

### **1. Name of the veterinary medicinal product**

Euthanimal 20%, 200 mg/ml solution for injection

### **2. Composition**

Each ml contains

#### **Active substance:**

Sodium pentobarbital 200 mg (equivalent to 182 mg pentobarbital)

#### **Excipients:**

Benzyl alcohol (E 1519) 20.0 mg

Ethanol 80.0 mg

Ponceau R4 (E 124) 0.02 mg

Clear red solution.

### **3. Target species**

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

### **4. Indications for use**

For 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 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.

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 "Withdrawal periods") 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 "Withdrawal periods").

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.

Pregnancy:

No specific information is available.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

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.

Major incompatibilities:

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

**7. 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) <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Convulsion Hiccup Vomiting

	Agonal breathing (gaspings) <sup>2</sup>
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<sup>1</sup> In cattle, mostly due to underdosing.

<sup>2</sup> One or few gasping respirations occur after cardiac arrest.

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 the local representative of the marketing authorisation holder 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 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.

## **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 must be taken to avoid perivascular administration (e.g. by using intravenous catheter).

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.

#### **10. 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.

#### **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 label after Exp. The expiry date refers to the last day of that month.

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

When the vial is broached for the first time, the date on which any veterinary medicinal product remaining in the vial is to be discarded should be filled out in the space provided on the label.

#### **12. Special precautions for disposal**

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 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**

Vm 36408/3050

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.

#### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **16. Contact details**

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

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

Local representatives and contact details to report suspected adverse reactions:

DUGV (UK) Ltd. Union House  
111 New Union Street  
Coventry, CV1 2NT  
[uksales@dugganvet.com](mailto:uksales@dugganvet.com)

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

## **<17. Other information>**

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Approved: 19 November 2024