ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Polystyrene package or carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthanimal 40%, 400 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance:
Sodium pentobarbital 400 mg (equivalent to 365 mg pentobarbital)

Excipients:
Benzyl alcohol (E 1519) 20.0 mg
Ethanol 80.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

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

6. INDICATION(S)

For euthanasia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle, horses, pigs, goats, sheep, cats and dogs:
100 mg/kg (corresponding to 0.25 ml/kg) via fast intravenous injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Not applicable.

Read the package leaflet before use.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use for anaesthesia.

Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use by 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

This medicinal product is dangerous to humans and animals. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

Medicine for the exclusive use of the veterinary surgeon. Not for sale to the public.
The administration and custody of the medicine should only be carried out by the veterinary surgeon.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder
Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands

DISTRIBUTED IN THE UK BY
DUGV (UK) Ltd. Union House,
111 New Union Street,
Coventry, CV1 2NT
uksales@dugganvet.com

16. MARKETING AUTHORISATION NUMBER

Vm 36408/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthanimal 40%, 400 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance:
Sodium pentobarbital 400 mg (equivalent to 365 mg pentobarbital)

Excipients:
Benzyl alcohol (E 1519) 20.0 mg
Ethanol 80.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

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

6. INDICATION(S)

For euthanasia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle, horses, pigs, goats, sheep, cats and dogs:
100 mg/kg (corresponding to 0.25 ml/kg) via fast intravenous injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Not applicable.

Read the package leaflet before use.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use for anaesthesia.

Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use by 28 days.
Once broached, use by __ . __ . ____

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

This medicinal product is dangerous to humans and animals. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder
Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands

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16. MARKETING AUTHORISATION NUMBER

Vm 36408/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Euthanimal 40%, 400 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel: 0031 348 – 416945
E-mail: alfasan@wxs.nl

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthanimal 40%, 400 mg/ml solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains

Active substance:

Sodium pentobarbital	400 mg (equivalent to 365 mg pentobarbital)

Excipients:

Benzyl alcohol (E 1519)	20.0 mg
Ethanol	80.0 mg
Ponceau 4R (E 124)	0.02 mg

Clear red solution for injection.

4. INDICATION

For euthanasia.

5. CONTRAINDICATIONS

Do not use for anaesthesia.

6. ADVERSE REACTIONS

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.

Common (more than 1 but less than 10 animals in 100 animals treated):
- Vocalisation
- Muscle twitching

Rare (more than 1 but less than 10 animals in 10,000 animals treated):
- Excitation
- Leg movements
- Defecation and urine loss
- Gasping (in cattle), mostly due to underdosing

Very rare (less than 1 animal in 10,000 animals treated, including isolated reports):
- Convulsions
- Contraction of the diaphragm
- Vomiting
- One or few gasping respirations occur after cardiac arrest

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 inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle, horses, pigs, goats, sheep, cats and dogs:100 mg/kg (corresponding to 0.25 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 less than 20 kg due to the highly concentrated nature of the product and increased risk of pain and irritation if administered perivascularly.

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 PERIOD(S)

Not applicable.

Appropriate measures need to be taken to assure that carcasses and edible products of animals injected with this 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 container: 28 days.
When the vial is broached for the first time, the date on which any product remaining in the vial is to be discarded should be filled out in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Carcasses and edible products of animals injected with this product may never enter the food chain (see section 10) and should be disposed of in accordance with national legislation.
Carcasses or parts of the carcass of animals euthanised with this product should not be fed to other animals due to the risk of secondary intoxication (see section 10).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Medicine for the exclusive use of the veterinary surgeon. Not for sale to the public.
The administration and custody of the medicine should only be carried out by the veterinary surgeon.

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 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 product.

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

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

Handle the 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 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 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 product is flammable, keep away from sources of ignition. Do not smoke.

Information for the health professional in case of <u>exposure</u>:
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 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 2.5 ml of product) has been reported to be fatal in humans. Treatment should be supportive with appropriate intensive therapy and maintenance of respiration.

<u>Pregnancy</u>:
No specific information is available.
The use of this product in pregnant animals is left to the judgement of the veterinarian.

Interaction with other medicinal products and other forms of interaction:
CNS depressants (narcotics, phenothiazines, antihistamines, etc.) may increase the effect of pentobarbital.

Overdose (symptoms, emergency procedures, 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 product, double dosage is discouraged, as this will not result in a faster or better euthanasia.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

This medicinal product is dangerous to humans and animals. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2023

15. OTHER INFORMATION

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.

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