

ANNEX II
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton/containing 12 x 100 ml glass vials or 12 x 50 ml glass vials and cardboard/containing 1 x 50 ml or 1 x 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Release
300 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of the solution for injection contains:
Pentobarbital sodium 300 mg

3. PACKAGE SIZE

1 x 50 ml
12 x 50 ml
1 x 100 ml
12 x 100 ml

4. TARGET SPECIES

Horses, ponies, cattle, swine, dogs, cats, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chicken, pigeons, birds, snakes, tortoises, lizards, frogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intravenous, intracardial, intraperitoneal or intrapulmonary use.

7. WITHDRAWAL PERIODS

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 consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 63 days.

9. SPECIAL STORAGE PRECAUTIONS

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

Accidental self-injection is dangerous.
Read the package leaflet before use.

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

WDT - Wirtschaftsgenossenschaft deutscher Tierärzte eG

14. MARKETING AUTHORISATION NUMBERS

Vm 32829/3002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 100 ml glass vials or 50 ml glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Release
300 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of the solution for injection contains:
Pentobarbital sodium 300 mg

3. TARGET SPECIES

Horses, ponies, cattle, swine, dogs, cats, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chicken, pigeons, birds, snakes, tortoises, lizards, frogs

4. ROUTES OF ADMINISTRATION

Intravenous, intracardial, intraperitoneal or intrapulmonal use.
Accidental self-injection is dangerous.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

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 consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 63 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

WDT - Wirtschaftsgenossenschaft deutscher Tierärzte eG

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Release
300 mg/ml, solution for injection

2. Composition

Each ml of solution for injection contains:

Active substance:

Pentobarbital sodium 300 mg

Excipient:

Patent blue V (E131) 0.001 mg

A clear, light blue solution.

3. Target species

Horses, ponies, cattle, swine, dogs, cats, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chicken, pigeons, birds, snakes, tortoises, lizards, frogs

4. Indications for use

Euthanasia in animals.

5. 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.

6. Special warnings

Special warnings:

The intraperitoneal route of administration may cause a prolonged onset of action with an increased risk of adverse effects. Prior sedation is advisable.

The intrapulmonary route of administration may cause a prolonged onset of action with an increased risk of adverse effects and should be reserved for cases where other routes of administration are not possible. Prior sedation is mandatory before this route of administration is employed.

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 in order that spontaneous recovery sometime later, does not occur.

Special precautions for safe use in the target species:

Venomous snakes are best euthanised by intracoelomic injections of sodium pentobarbital solution with judicious use of prior sedation in order to minimise danger to humans.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Pentobarbital is a potent drug which is toxic in man – 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 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 3.3 ml of product) has been reported to be fatal in humans.

Avoid direct contact with the skin and eyes, including hand-to-eye contact.

Wear suitable protective gloves when handling this 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 should avoid contact with the veterinary medicinal product.

This product should be used only 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.

In the event of accident 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 patient unattended.

DO NOT DRIVE as sedation may occur.

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

To the physician: Maintain airways and give symptomatic and supportive treatment.

Special precautions for the protection of the environment:

Carcasses of animals euthanised with this product should be disposed of in accordance with national legislation. Carcasses of animals euthanised with this product should not be fed to other animals due to the risk of secondary intoxication.

Pregnancy:

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, euthanised separately.

Interaction with other medicinal products and other forms of interaction:

CNS depressant drugs (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.

Major incompatibilities:

The following drugs have been reported to be incompatible with pentobarbital sodium: insulin (regular), norepinephrine bitartrate, oxytetracycline HCl, penicillin G and streptomycin sulphate. Compatibility is dependent upon factors such as pH, concentration, temperature, and diluents used.

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

7. Adverse events

Horses, ponies, cattle, swine, dogs, cats, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chicken, pigeons, birds, snakes, tortoises, lizards, frogs:

Very common (>1 animal / 10 animals treated):
Agonal breathing ¹ , Cough ¹ , Respiratory distress ¹
Undetermined frequency (cannot be estimated from the available data):
Twitching ²

¹ after administration by the intra-pulmonary route

² minor, after injection

Death may be delayed if the injection is administered perivascularly. Barbiturates can be irritating when administered subcutaneously or perivascularly.

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.

8. Dosage for each species, routes and method of administration

Intravenous, intracardial, intraperitoneal or intrapulmonary use.

Horses, Ponies

Intravenous (rapid injection)	900 mg/10 kg bodyweight (accordingly 3 ml/10 kg bw)
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Cattle

Intravenous (rapid injection)	450 mg/10 kg to 900 mg/10 kg bodyweight (accordingly, 1.5-3 ml/10 kg bw)
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Swine

- Intravenous via ear vein (no restraint or restraint by using a loop for the upper jaw) - Intravenous via Vena cava cran. (restraint with a loop for the upper jaw or in piglets restraint between the thighs of a second person)	450 mg/5 kg up to 30 kg bodyweight (1.5 ml/5 kg bw) 450 mg/10 kg above 30 kg bodyweight (1.5 ml/10 kg bw)
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Dogs

Intravenous: continuous injection till sleep, then rapid injection of the remaining quantity	150 mg/kg bodyweight (accordingly 0.5 ml/kg bw)
Intracardiac, intrapulmonary and intraperitoneal	450 mg/kg bodyweight (accordingly 1.5 ml/kg bw)

Cats

Intravenous: continuous injection till sleep, then rapid injection of the remaining quantity	150 mg/kg bodyweight (accordingly 0.5 ml/kg bw)
Intracardiac, intrapulmonary and intraperitoneal	450 mg/kg bodyweight (accordingly 1.5 ml/kg bw)

Minks, Polecats

Intravenous	450 mg/animal (accordingly 1.5 ml per animal)
Intracardiac, intrapulmonary injection with a long needle (4 cm) from the caudal part of the breastbone (xiphoid process, xiphisternum) in cranio-dorsal direction	450 mg/animal (accordingly 1.5 ml per animal)

Hares, Rabbits, Guinea Pigs, Hamsters, Rats, Mice

Intravenous, intracardiac	300 mg/kg bodyweight (accordingly 1 ml/kg bw)
Intrapulmonary	300 mg/kg bodyweight (accordingly 1 ml/kg bw)
Intraperitoneal	600 mg/kg bodyweight (accordingly 2 ml/kg bw)

Chicken, Pigeons, Birds

Intravenous	450 mg/kg bodyweight (accordingly 1.5 ml/kg bw)
Intrapulmonary	450 mg/kg bodyweight (accordingly 1.5 ml/kg bw)

Snakes, Tortoises, Lizards and Frogs up to 5 kg

Injection into the cavity near the heart. Death occurs after 5 to 10 minutes.	Minimal dose rate: 60 mg/kg body weight Average: 300 – 450 mg/animal (accordingly 1.0 ml to 1.5 ml/animal)
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9. Advice on correct administration

The intravenous route of administration should be the route of choice, if possible. Where intravenous administration is impossible, and **only** following appropriate sedation, the product may be administered via the intracardiac route in all named species except the avian ones.

Only if intracardiac administration is not possible, should administration via the intraperitoneal route be used and again only following appropriate sedation of the animal concerned. This route is not suitable for horses, ponies, cattle or pigs.

Intrapulmonary administration should be used only as a **last resort** and only once the animal has been sedated and shows no response to noxious stimuli. This route is not suitable for horses, ponies, cattle or pigs

The applicable dose depends on animal species and route of administration. Therefore, please follow the instructions described in the dosage scheme carefully.

The intravenous injection in companion animals should be carried out with a continuous injection rate until unconsciousness occurs.

In horses and cattle, veterinary medicinal product should be injected under pressure as fast as possible.

Method of choice in birds is the intravenous injection. If venipuncture cannot be performed due to e.g. haematoma, collapse of cardiovascular system, intrapulmonary injection should be done. This is performed by inserting the cannula in dorso-ventral direction on the left or right side of the backbone into the lung (3rd or 4th intercostal segment between backbone and scapula).

In swine, it was shown that there might be 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. 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 consumption.

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 and carton.

The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 63 days.

12. Special precautions for disposal

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

This veterinary medicinal product should not enter water courses as pentobarbital sodium may be dangerous for fish and other aquatic organisms.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 32829/3002

100 ml multi-dose vial, colourless Type I glass, with halogenic butyl rubber stopper and aluminium overseal. Available in cartons containing 1 or 12 multidose vials.

50 ml multi-dose vial, colourless Type I glass, with halogenic butyl rubber stopper and aluminium overseal. Available in cartons containing 1 or 12 multidose vials.

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.

16. Contact details

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

WDT - Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstrasse 14
30827 Garbsen
Germany
Tel.: +49 (0)5131 705 4010
E-Mail: pharmakovigilanz@wdt.de

<Local representatives< and contact details to report suspected adverse reactions>:>

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

Gavin Hall
Approved: 11 December 2024