

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Release 300 mg/ml, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance: pentobarbital sodium 300 mg

Excipient: patent blue V

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

A clear, blue solution.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

For euthanasia in animals.

4.3 Contraindications

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

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.

4.4 Special warnings for each target species

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.

The intraperitoneal route of administration may cause a prolonged onset of action with an increased risk of adverse effects noted in 4.6. Prior sedation is advisable.

The intrapulmonary route of administration may cause a prolonged onset of action with an increased risk of adverse effects noted in 4.6 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.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

Minor muscle twitching may occur after injection. In cattle, gasping may occur in rare cases if pentobarbital sodium is administered below the recommended dose. Death may be delayed if the

injection is administered perivascularly. Barbiturates can be irritating when administered subcutaneously or perivascularly.

Administration by the intrapulmonary route is highly likely to cause coughing, gasping and respiratory distress.

4.7 Use during pregnancy, lactation or lay

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 fetus 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 fetus is to be examined for signs of life and, if necessary, euthanised separately.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

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 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, Release 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.

. Horses, Ponies

Intravenous (rapid injection)	900 mg/10kg 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)	450mg/5kg up to 30kg bodyweight (1.5ml/5kg bw)
- Intravenous via Vena cava cran. (restraint with a loop for the upper jaw or in piglets restraint between the thighs of a second person)	450mg/10kg above 30kg bodyweight (1.5 ml/10kg bw)

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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4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 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.

5. <PHARMACOLOGICAL><IMMUNOLOGICAL> PROPERTIES

Pharmacotherapeutic group: Barbiturates for Euthanasia
ATCvet code: QN51AA01

<5.1 Pharmacodynamic properties>

Pentobarbital is an anaesthetic agent and belongs to the group of barbituric acid derivatives. The LD₅₀ in dogs and cats is approximately 40 to 60 mg/kg bodyweight when injected intravenously. 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.

<5.2 Pharmacokinetic particulars>

Pentobarbital distributes rapidly to all body tissues (except fatty tissue) with highest concentrations found in the liver.

Pentobarbital crosses the placenta and enters milk.

The elimination half-life in small ruminants has been reported to be approximately 1 hour, in cats 2 to 7.5 hours and in dogs 7 to 12.5 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol

Ethanol (96 per cent)

Water for injection

Patent blue V

6.2 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.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 63 days

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

WDT – Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemenstraße 14
30827 Garbsen
Germany

8. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 32829/4000

DE: 400883.00.00

IE: VPA 10660/001/001

HU: MgSzH ATI (100ml)

AT: 8-00753

ES: 3083 ESP

BE: BE-V325631

NL: REG NL 101841

PT: 811/01/14RFVPT

IT: 104714011

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 August 2008

Date of last renewal: 23 April 2012

10. DATE OF REVISION OF THE TEXT

05/2019

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.