ANNEX III

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 Cartboard/containing 1 x 50 ml or 1 x 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Release300 mg/ml solution for injection
Pentobarbital sodium

2. STATEMENT OF ACTIVE SUBSTANCES

Pentobarbital sodium 300 mg/ml
Patent blue V

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

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

6. INDICATION(S)

Euthanasia in animals.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous, intracardial, intraperitoneal or intrapulmonal injection.
Read the package leaflet before use.

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP (mm/yyyy)
Shelf life after first opening: 63 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

Dispose of waste material in accordance with local requirements.

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

WDT-Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstr. 14, 30827 Garbsen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32829/4000

17. MANUFACTURER'S BATCH NUMBER

Batch 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

Release300 mg/ml solution for injection
Pentobarbital sodium

2. STATEMENT OF ACTIVE SUBSTANCES

Pentobarbital sodium 300 mg/ml
Patent blue V

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

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

6. INDICATION(S)

Euthanasia in animals.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous, intracardial, intraperitoneal or intrapulmonal injection.
Read the package leaflet before use.

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP (mm/yyyy)
Shelf life after first opening: 63 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

Dispose of waste material in accordance with local requirements.

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

WDT-Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstr. 14, 30827 Garbsen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32829/4000

17. MANUFACTURER'S BATCH NUMBER

Batch number

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
RELEASE 300 mg/ml

Solution for Injection, pentobarbital sodium

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:
WDT – Wirtschaftsgenossenschaft deutscher Tierärzte eG,
Siemensstr. 14, 30827 Garbsen, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Release 300 mg/ml solution for injection
Pentobarbital sodium

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Pentobarbital sodium 300 mg/ml
patent blue V

4. INDICATION(S)

Euthanasia in animals.

5. 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 chelonian as the time to death may be unnecessarily prolonged compared with intravenous administration.

6. ADVERSE REACTIONS

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 or not accomplished if the injection is administered perivascularly. Barbiturates can be very irritating if administered subcutaneously or perivascularly. Administration by the intrapulmonary route is highly likely to cause coughing, gasping and respiratory distress.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

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

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

. Horses, Ponies

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

. Cattle

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

. 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)	450mg/5kg up to 30kg bodyweight (1.5ml/5kg bw) 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 (accordingly1.5 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)

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 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.

10. 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.

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.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Shelf life after first opening the container: 63 days.

12. SPECIAL WARNING(S)

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. 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 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.

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.

Interaction with other medicinal products and other forms of interaction:
CNS depressant drugs (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.

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.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

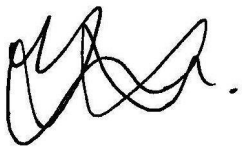
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2019

<15. OTHER INFORMATION>

50ml, 12 x 50ml, 100 ml, 12 x 100 ml

Not all pack sizes may be marketed.



Approved: 30 October 2019