*[Version 9.1,11/2024]*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exagon 400 mg/ml solution for injection (AT, CZ, DE, EE, EL, ES, LT, LV, PL, PT, RO, SI, SK)
Eutavet, 400 mg/ml solution for injection (IT)
Exagon solution for injection (FR)
Exagon vet. 400 mg/ml solution for injection (DK, IS, NO, SE)
Eutabarb vet. 400 mg/ml solution for injection (FI)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substances:**
Pentobarbital sodium 400.0 mg
(equivalent to 364.6 mg pentobarbital)

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Propylene glycol | 200.0 mg |
| Ethanol (96 per cent) | 80.0 mg |
| Benzyl alcohol (E 1519) | 20.0 mg |
| Patent Blue V (E 131) | 0.01 mg |
| Water for injections | |

Clear, blue solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

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

### 3.2 Indications for use for each target species

Euthanasia

### 3.3 Contraindications

Do not use for anaesthesia.

Do not use for intracoelomic injection in chelonia as the time to death may be unnecessarily prolonged compared with intravenous administration.

### 3.4 Special warnings

To reduce the risk of induction excitement, it is recommended to perform euthanasia in a quiet area.
When an aggressive animal is to undergo euthanasia, premedication with a more easily administered (oral, subcutaneous or intramuscular) sedative is recommended.

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).

The intraperitoneal route of administration may cause a prolonged onset of action with an increased risk of induction excitement. Intraperitoneal administration must only be used following appropriate sedation. Measures must be taken to avoid administration into the spleen or organs/tissue with low capacity for absorption. This route of administration is only suitable for small mammals.

Intracardiac injection must only be used if the animal is heavily sedated, unconscious or anesthetized.

The intrapulmonary route of administration may cause a prolonged onset of action with an increased risk of adverse effects noted in 3.6 and must be reserved for cases where other routes of administration are not possible. Intrapulmonary administration may only be used in poultry, pigeons, birds, snakes, tortoises, lizards and frogs. Animals must be heavily sedated, unconscious or anesthetized before this route of administration is employed. Do not use intrapulmonary administration in any other target animal species.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:
Ingestion of euthanized animals by other animals may lead to intoxication, anaesthesia and even death. Barbiturates are highly persistent in carcasses and also stable to cooking temperature.
After administration of this veterinary medicinal product, recumbency 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 safe distance from the animal to avoid injury.

**Horse, cattle:**
In horses and cattle, premedication with an appropriate sedative must be used to produce profound sedation before euthanasia, and an alternative method of euthanasia should be available.

**Swine:**
In individual cases – especially in restrained animals – agitation/excitation could occur during administration resulting in accidental paravenous administration of the veterinary medicinal product. Due to the difficulty of safe intravenous injections in swine adequate sedation of the animal before IV administration of pentobarbital is recommended. Intracardiac administration must only be used if the animal is heavily sedated, unconscious or anesthetized. Application via marginal ear vein should at least initially be performed without fixation. The animals should be restrained between the legs of an assisting person. If fixation is necessary, a snout rope should be used.

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 this 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 2.5 ml of the veterinary medicinal 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 veterinary medicinal product – pentobarbital can be absorbed via skin and mucosa.

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). People with known hypersensitivity to pentobarbital or to any other ingredient should avoid contact with the veterinary medicinal product.

This veterinary medicinal product should only be used 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 veterinary medicinal 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 veterinary medicinal product is flammable. Keep away from sources of ignition. Do not smoke.

To the physician: Urgent care should be taken to maintain airways and cardiac function. In case of severe intoxication, additional measures should be taken to enhance the elimination of the barbiturate. Give symptomatic and supportive treatment.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Due to the risk of secondary intoxication animals euthanized with the veterinary medicinal product should not be fed to other animals but should be disposed of in accordance with national legislation and in a manner securing that other animals cannot have access to the carcasses.

### 3.6 Adverse events

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

| | |
|---|---|
| Undetermined frequency (cannot be estimated from the available data): | Twitching[1]<br>Cough[2], Agonal breathing[2], Respiratory distress[2]<br>Excitation[3] |

[1] Minor muscle twitching.
[2] After administration by the intrapulmonary route.
[3] During introduction of sleep. Pre-medication/pre-sedation strongly reduces the risk for excitation during introduction of sleep.

In cattle, gasping may occur in rare cases if pentobarbital is administered below the recommended dose.

Death may be delayed, if the injection is administered perivascularly. Perivascular or subcutaneous administration can result in tissue irritation.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. Use only according to the benefit-risk assessment by the responsible veterinarian.

Pregnancy:
The increased body weight of pregnant animals should be taken into account in the dose calculation. Whenever possible, the veterinary medicinal 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, euthanized separately.

### 3.8 Interaction with other medicinal products and other forms of interaction

Although premedication with sedatives may delay the desired effect of the veterinary medicinal product due to decreased circulatory function this may not be clinically noticeable since CNS depressant drugs (opioids, α2 adrenoreceptor agonists, phenothiazines, etc.) can also increase the effect of pentobarbital.

### 3.9 Administration routes and dosage

The intravenous route of administration should be the route of choice and adequate sedation should be applied if deemed necessary by the veterinary surgeon. For horses and cattle premedication is mandatory.
Where intravenous administration is difficult, and only following deep sedation or anaesthesia, the veterinary medicinal product may be administered via the intracardiac route. Alternatively, for small animals only, administration via the intraperitoneal route could be used, but only following appropriate sedation.
Intrapulmonary administration must only be used as a **last resort** and only if the animal is heavily sedated, unconscious or anesthetized and shows no response to noxious stimuli. This route of administration may only be used in poultry, pigeons, birds, snakes, tortoises, lizards and frogs.

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 small animals should be carried out with a continuous injection rate until unconsciousness occurs.

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 could be an option. In birds, intrapulmonary injection is performed by inserting the canula in dorso-ventral direction on the left or right side of the backbone into the lung (3$^{rd}$ or 4$^{th}$ intercostal segment between backbone and scapula).

In horses, cattle and swine pentobarbital must be injected as a rapid bolus.

For easier and less painful injection into the marginal ear vein in swine the veterinary medicinal product should be diluted with sterile, isotonic sodium chloride (0.9%) solution at a mix ratio 1:1.

**Horses, ponies**
1 ml per 4.5 – 5 kg bodyweight, intravenous as a rapid bolus

**Cattle**
1 - 2 ml per 10 kg bodyweight, intravenous as a rapid bolus

**Swine**
Amounts to be administered:

**Vena cava cranialis:** intravenous as a rapid bolus
**0.1 ml/kg** bodyweight in animals weighing **> 30 kg**
**0.2 ml/kg** bodyweight in animals weighing **< 30 kg**

**Marginal ear vein:** intravenous as a rapid bolus
**0.1 ml/kg** bodyweight in animals weighing **> 30 kg**
**0.2 ml/kg** bodyweight in animals weighing **< 30 kg**
Dilution with sterile, isotonic NaCl (0.9%)-solution at a mix ratio of 1:1 is necessary.

**Intracardiac route:**
**0.1 ml/kg** bodyweight in animals weighing **> 30 kg**
**0.2 ml/kg** bodyweight in animals weighing **< 30 kg**

Administration routes:
*Animals grouped by weight and routes of administration:*

**Piglet (up to 8 kg):**
Intravenous (Vena cava cranialis) or intracardiac administration

**Weaners (8 - 25 kg), growers (25 - 40 kg), fatteners (40 - 100 kg):**
Intravenous (Vena cava cranialis or marginal ear vein) or intracardiac administration

**Boars and sows (more than 100 kg):**
Intravenous administration (marginal ear vein)

*Fixation:*
If possible, fixation should be avoided or at least limited to a minimum.

If fixation is necessary, a snout rope should be used.

**Dogs**
**Intravenous administration:** continuous injection (approx. 1.2 ml/s) until loss of consciousness, then the rest administered as a rapid bolus:
1 ml per 3 – 5 kg bodyweight

**Intracardiac and intraperitoneal administration**:
1 ml per 3 – 4 kg bodyweight

**Cats**
**Intravenous administration:** continuous injection until the animal loses consciousness, then the rest administered as a rapid bolus:
1 ml per 2 – 3 kg bodyweight

**Intracardiac and intraperitoneal administration**:
1 ml per kg bodyweight

**Minks, polecats**
1 ml per animal **intravenously**

1 ml per animal **intracardially** with a long canula (approx. 4 cm) injected in cranial and slightly dorsal direction from the caudal end of the sternum *(processus xiphoideus)*.

**Hares, rabbits, guinea pigs, hamsters, rats, mice**
1 ml per 1 – 2 kg bodyweight **intravenously, intracardially**

1 ml per 0.5 – 1 kg bodyweight **intraperitoneally**

**Poultry, pigeons, ornamental birds**
1 – 2 ml per kg bodyweight **intravenously**

1 – 2 ml per kg bodyweight **intrapulmonarily**

**Snakes, tortoises, lizards, frogs**
Depending on the size of the animal inject 0.5 to 1.0 ml into the thoracic cavity near the heart; death is to be expected after about 5 to 10 minutes.

The stopper must not be punctured more than 25 times.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of accidental administration of the veterinary medicinal product to an animal, which should not be euthanized, adequate measures should be taken to maintain airways and circulation. The administration of oxygen and the use of analeptics are appropriate.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

### 3.12 Withdrawal periods

Do not use in animals intended for human or animal consumption.
Adequate measures must be taken to ensure that carcasses of animals treated with this veterinary medicinal product and the by-products of these animals do not enter the food chain and are not used for human or animal consumption.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QN51AA01

### 4.2 Pharmacodynamics

Pentobarbital is a narcotic belonging to the group of barbituric acid derivatives. The $LD_{50}$ in dogs and cats is approximately 40 to 60 mg/kg bodyweight when injected intravenously.
For the euthanasia of animals highly excessive doses are administered. 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 veterinary medicinal product.

### 4.3 Pharmacokinetics

The distribution of pentobarbital in the organism is quite even. The highest concentrations were found in the liver, in adipose tissue no accumulation could be shown.
Pentobarbital passes the placental barrier and also enters milk.
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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products except sterile, isotonic sodium chloride (0.9%) solution.

### 5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 28 days

Shelf-life of the 1:1 diluted solution for intravenous injection into the marginal ear vein in swine: 2 hours

### 5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze. Protect from light.

### 5.4 Nature and composition of immediate packaging

Cardboard box with clear glass vial (type II) with bromobutyl rubber stopper and aluminium cap.

Package sizes:
Cardboard box containing 1x 100 ml vial
Cardboard box containing 5 x 100 ml vials

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exagon 400 mg/ml solution for injection (AT, CZ, DE, EE, EL, ES, LT, LV, PL, PT, RO, SI, SK)
Eutavet 400 mg/ml solution for injection (IT)
Exagon solution for injection (FR)
Exagon vet. 400 mg/ml solution for injection (DK, IS, NO, SE)
Eutabarb vet. 400 mg/ml solution for injection (FI)

Pentobarbital sodium

## 2. STATEMENT OF ACTIVE SUBSTANCES

Pentobarbital sodium 400 mg/ml
(equivalent to 364.6 mg/ml pentobarbital)

## 3. PACKAGE SIZE

100 ml
5 x 100 ml

## 4. TARGET SPECIES

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

## 5. INDICATIONS

Euthanasia

## 6. ROUTES OF ADMINISTRATION

Intravenous, intracardiac, intraperitoneal, intrapulmonary use.

## 7. WITHDRAWAL PERIODS

Adequate measures must be taken to ensure that carcasses of animals treated with this veterinary medicinal product and the by-products of these animals do not enter the food chain and are not used for human or animal consumption.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use by 28 days.
Once diluted, use by 2 hours.

## 9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not freeze. Protect from light.

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

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

VetViva Richter (logo)

## 14. MARKETING AUTHORISATION NUMBERS

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**100 ml clear glass vial (type II) with bromobutyl rubber stopper and aluminium cap**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exagon 400 mg/ml solution for injection (AT, CZ, DE, EE, EL, ES, LT, LV, PL, PT, RO, SI, SK)
Eutavet 400 mg/ml solution for injection (IT)
Exagon solution for injection (FR)
Exagon vet. 400 mg/ml solution for injection (DK, IS, NO, SE)
Eutabarb vet. 400 mg/ml solution for injection (FI)

Pentobarbital sodium

## 2. STATEMENT OF ACTIVE SUBSTANCES

Pentobarbital sodium 400 mg/ml

## 3. TARGET SPECIES

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

## 4. ROUTES OF ADMINISTRATION

Intravenous, intracardiac, intraperitoneal, intrapulmonary.
Euthanasia
Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

## 6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days by…
Once diluted, use by 2 hours.

## 7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not freeze. Protect from light.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

## 9. BATCH NUMBER

Lot {number}

100 ml

**B. PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Exagon 400 mg/ml solution for injection (AT, CZ, DE, EE, EL, ES, LT, LV, PL, PT, RO, SI, SK)
Eutavet, 400 mg/ml solution for injection (IT)
Exagon solution for injection (FR)
Exagon vet. 400 mg/ml solution for injection (DK, IS, NO, SE)
Eutabarb vet. 400 mg/ml solution for injection (FI)

## 2. Composition

Each ml contains:

**Active substance:**

| | |
|---|---|
| Pentobarbital sodium | 400.0 mg |
| (equivalent to 364.6 mg pentobarbital) | |

**Excipients:**

| | |
|---|---|
| Propylene glycol | 200.0 mg |
| Ethanol (96 per cent) | 80.0 mg |
| Benzyl alcohol (E 1519) | 20.0 mg |
| Patent Blue V (E 131) | 0.01 mg |

Clear, blue solution.

## 3. Target species

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

## 4. Indications for use

Euthanasia

## 5. Contraindications

Do not use for anaesthesia.

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:
To reduce the risk of induction excitement, it is recommended to perform euthanasia in a quiet area.
When an aggressive animal is to undergo euthanasia, premedication with a more easily administered (oral, subcutaneous or intramuscular) sedative is recommended.

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).

The intraperitoneal route of administration may cause a prolonged onset of action with an increased risk of induction excitement. Intraperitoneal administration must only be used following appropriate sedation. Measures must be taken to avoid administration into the spleen or organs/tissue with low capacity for absorption. This route of administration is only suitable for small mammals.

Intracardiac injection must only be used if the animal is heavily sedated, unconscious or anesthetized.

The intrapulmonary route of administration may cause a prolonged onset of action with an increased risk of adverse effects (listed under 'Adverse events') and must be reserved for cases where other routes of administration are not possible. Intrapulmonary administration may only be used in poultry, pigeons, birds, snakes, tortoises, lizards and frogs. Animals must be heavily sedated, unconscious or anesthetized before this route of administration is employed. Do not use intrapulmonary administration in any other target animal species.

Special precautions for safe use in the target species:
Ingestion of euthanized animals by other animals may lead to intoxication, anaesthesia and even death. Barbiturates are highly persistent in carcasses and also stable to cooking temperature.
After administration of this veterinary medicinal product, recumbency 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 safe distance from the animal to avoid injury.

**Horse, cattle:**
In horses and cattle, premedication with an appropriate sedative must be used to produce profound sedation before euthanasia, and an alternative method of euthanasia should be available.

**Swine:**
In individual cases – especially in restrained animals – agitation/excitation could occur during administration resulting in accidental paravenous administration of the veterinary medicinal product. Due to the difficulty of safe intravenous injections in swine adequate sedation of the animal before IV administration of pentobarbital is recommended. Intracardiac administration must only be used if the animal is heavily sedated, unconscious or anesthetized. Application via marginal ear vein should at least initially be performed without fixation. The animals should be restrained between the legs of an assisting person. If fixation is necessary, a snout rope should be used.

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 this 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 2.5 ml of the veterinary medicinal 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 veterinary medicinal product – pentobarbital can be absorbed via skin and mucosa.
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).

People with known hypersensitivity to pentobarbital or to any other ingredient should avoid contact with the veterinary medicinal product.

This veterinary medicinal product should only be used 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 veterinary medicinal 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 veterinary medicinal product is flammable. Keep away from sources of ignition. Do not smoke.

To the physician: Urgent care should be taken to maintain airways and cardiac function. In case of severe intoxication, additional measures should be taken to enhance the elimination of the barbiturate. Give symptomatic and supportive treatment.

Other precautions:
Due to the risk of secondary intoxication animals euthanized with the veterinary medicinal product should not be fed to other animals but should be disposed of in accordance with national legislation and in a manner securing that other animals cannot have access to the carcasses.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. Use only according to the benefit-risk assessment by the responsible veterinarian.
The increased body weight of pregnant animals should be taken into account in the dose calculation. Whenever possible, the veterinary medicinal 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, euthanized separately.

Interaction with other medicinal products and other forms of interaction:
Although premedication with sedatives may delay the desired effect of the veterinary medicinal product due to decreased circulatory function this may not be clinically noticeable since CNS depressant drugs (opioids, α2 adrenoreceptor agonists, phenothiazines, etc.) can also increase the effect of pentobarbital.

Overdose:
In case of accidental administration of the veterinary medicinal product to an animal, which should not be euthanized, adequate measures should be taken to maintain airways and circulation. The administration of oxygen and the use of analeptics are appropriate.

<Special restrictions for use and special conditions for use:>

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products except sterile, isotonic sodium chloride (0.9%) solution.

## 7. Adverse events

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

Undetermined frequency (cannot be estimated from the available data):
Twitching[1], Cough[2], Agonal breathing[2], Respiratory distress[2], Excitation[3].

[1] Minor muscle twitching.
[2] After administration by the intrapulmonary route.
[3] During introduction of sleep. Pre-medication/pre-sedation strongly reduces the risk for excitation during introduction of sleep.

In cattle, gasping may occur in rare cases if pentobarbital is administered below the recommended dose.

Death may be delayed, if the injection is administered perivascularly. Perivascular or subcutaneous administration can result in tissue irritation.

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 its local representative 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

The intravenous route of administration should be the route of choice and adequate sedation should be applied if deemed necessary by the veterinary surgeon. For horses and cattle premedication is mandatory.
Where intravenous administration is difficult, and only following deep sedation or anaesthesia, the veterinary medicinal product may be administered via the intracardiac route. Alternatively, for small animals only, administration via the intraperitoneal route could be used, but only following appropriate sedation.
Intrapulmonary administration must only be used as a **last resort** and only if the animal is heavily sedated, unconscious or anesthetized and shows no response to noxious stimuli. This route of administration may only be used in poultry, pigeons, birds, snakes, tortoises, lizards and frogs.

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 small animals should be carried out with a continuous injection rate until unconsciousness occurs.

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 could be an option. In birds, intrapulmonary injection is performed by inserting the canula 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 horses, cattle and swine pentobarbital must be injected as a rapid bolus.

**Horses, ponies**
1 ml per 4.5 – 5 kg bodyweight, intravenous as a rapid bolus

**Cattle**
1 - 2 ml per 10 kg bodyweight, intravenous as a rapid bolus

**Swine**
Amounts to be administered:

**Vena cava cranialis:** intravenous as a rapid bolus
**0.1 ml/kg** bodyweight in animals weighing **> 30 kg**
**0.2 ml/kg** bodyweight in animals weighing **< 30 kg**

**Marginal ear vein:** intravenous as a rapid bolus
**0.1 ml/kg** bodyweight in animals weighing **> 30 kg**
**0.2 ml/kg** bodyweight in animals weighing **< 30 kg**
Dilution with sterile, isotonic NaCl (0.9%)-solution at a mix ratio of 1:1 is necessary.

**Intracardiac route:**
**0.1 ml/kg** bodyweight in animals weighing **> 30 kg**
**0.2 ml/kg** bodyweight in animals weighing **< 30 kg**

Administration routes:
*Animals grouped by weight and routes of administration:*

**Piglet (up to 8 kg):**
Intravenous (Vena cava cranialis) or intracardiac administration

**Weaners (8 - 25 kg), growers (25 - 40 kg), fatteners (40 - 100 kg):**
Intravenous (Vena cava cranialis or marginal ear vein) or intracardiac administration

**Boars and sows (more than 100 kg):**
Intravenous administration (marginal ear vein)

*Fixation:*
If possible, fixation should be avoided or at least limited to a minimum.

If fixation is necessary, a snout rope should be used.

**Dogs**
**Intravenous administration:** continuous injection (approx. 1.2 ml/s) until loss of consciousness, then the rest administered as a rapid bolus:
1 ml per 3 – 5 kg bodyweight

**Intracardiac and intraperitoneal administration**:
1 ml per 3 – 4 kg bodyweight

**Cats**
**Intravenous administration:** continuous injection until the animal loses consciousness, then the rest administered as a rapid bolus:
1 ml per 2 – 3 kg bodyweight

**Intracardiac and intraperitoneal administration**:
1 ml per kg bodyweight

**Minks, polecats**
1 ml per animal **intravenously**

1 ml per animal **intracardially** with a long canula (approx. 4 cm) injected in cranial and slightly dorsal direction from the caudal end of the sternum *(processus xiphoideus)*.

**Hares, rabbits, guinea pigs, hamsters, rats, mice**
1 ml per 1 – 2 kg bodyweight **intravenously, intracardially**

1 ml per 0.5 – 1 kg bodyweight **intraperitoneally**

**Poultry, pigeons, ornamental birds**
1 – 2 ml per kg bodyweight **intravenously**

1 – 2 ml per kg bodyweight **intrapulmonarily**

**Snakes, tortoises, lizards, frogs**
Depending on the size of the animal inject 0.5 to 1.0 ml into the thoracic cavity near the heart; death is to be expected after about 5 to 10 minutes.

The stopper must not be punctured more than 25 times.

## 9. Advice on correct administration

For easier and less painful injection into the marginal ear vein in swine the veterinary medicinal product should be diluted with sterile, isotonic sodium chloride (0.9%) solution at a mix ratio 1:1.

## 10. Withdrawal periods

Do not use in animals intended for human or animal consumption.
Adequate measures must be taken to ensure that carcasses of animals treated with this veterinary medicinal product and the by-products of these animals do not enter the food chain and are not used for human or animal consumption.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not freeze. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and cardboard box after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 28 days
Shelf-life after 1:1 dilution of solution for intravenous injection into the marginal ear vein in swine: 2 hours

## 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.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Pack sizes:
Cardboard box containing 1x 100 ml vial
Cardboard box containing 5 x 100 ml vials

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse events>:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

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

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

## <17. Other information>