

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

T 61 Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per mL:

Active substances:

Embutramide	200.00 mg
Mebezonium iodide	50.00 mg
Tetracaine hydrochloride	5.00 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Dimethylformamide	566.67 mg
Water for injection	

Solution for injection .Clear colorless to yellowish solution.

3. CLINICAL PARTICULARS

3.1 Target species

Dog, cat, mink, horse, pigeons, cage birds, small laboratory animals, and other animals.

3.2 Indications for use for each target species

For euthanasia of dogs, cats and other animals.

3.3 Contraindications

Do not inject in the pleural cavity.

Only use in animals that are unconscious.

Do not use in pregnant animals.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To be used only by veterinarians.

Exercise extreme care when using this veterinary medicinal product.

Only use this veterinary medicinal product in unconscious (anesthetized) animals. This is to prevent conscious animals from asphyxiating in the event of unfavorable absorption conditions.

In animals with heart failure or circulation problems, the effect may be delayed and less than expected due to slower transport to the target tissues. The occurrence of cardiac arrest may be delayed as a result. Intravenous administration must take place in such a way that the entire dose is administered intravenously. Use of an intravenous catheter is recommended.

Extravascular administration may delay the effect and lead to excitation; therefore, you should check for the return of signs of life and repeat the administration where necessary.

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

For the person administering the veterinary medicinal product:

This veterinary medicinal product is highly toxic, may lead to respiratory depression, cardiac arrest, and may be fatal! Prevent direct contact with the skin and the eyes, including hand-to-mouth contact and

hand-to-eye contact. Wearing gloves when handling the veterinary medicinal product is recommended. Immediately remove any contaminated clothing.

In the event that the veterinary medicinal product gets into contact with an open wound, the mucus membranes or the skin, wash the affected area immediately and thoroughly with water and soap, and rinse well.

If the veterinary medicinal product gets into the eyes, immediately rinse the eyes with clean running water for several minutes.

In the event of accidental self-injection, immediately express the pierced area, and wash the wound with sufficient water and soap. In the event of intramuscular injection, the relevant extremity must be tied off.

In the event of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Do not leave the relevant person alone.

Store this veterinary medicinal product in a safe and locked place.

For the doctor:

The concentrations of embutramide, mebezonium iodide and tetracaine hydrochloride in the veterinary medicinal product are such that the accidental injection or ingestion of small amounts may have serious consequences that may be fatal to humans. Emergency measures should be aimed at preserving respiration and cardiac function, and include cardiopulmonary resuscitation and, where necessary, hemodialysis and supportive therapy (atropine, neostigmine, N-acetylcysteine), depending on the degree of exposure and symptoms.

Special precautions for the protection of the environment:

Feeding euthanized animals can lead to secondary toxicity in scavengers. Do not administer to animals which may enter the food chain of wild fauna. In the case of death or euthanasia of treated animals, make sure that these do not end up with wild fauna.

3.6 Adverse reactions

Large (farm) animals, dogs, cats, mink, other animals, such as birds and small laboratory animals:

Very rare (<1 animal/10,000 animals treated, including isolated reports):	Convulsion; Excitation; Vascular disorder ^{1,2} ; Pulmonary congestion ² ; Pulmonary edema ² ; Hemolysis ²

¹ Such as lesions of the endothelium

² Histopathological changes

Reporting adverse reactions is important. This allows continuous safety monitoring of a veterinary medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il/>

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use (whether during the entire pregnancy or any part thereof).

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Route(s) of administration:

Intravenous, intra-pulmonary.

To be applied by veterinarian only.

T61 Veterinary must be applied to animals under anesthesia. This is in order to prevent the animal from undergoing live suffocation should the T61 Veterinary be applied incorrectly or not be properly absorbed. In using T61 Veterinary, exercise utmost care. Intravenous administration is to be carried out in such manner that the dose is fully introduced intravenously. The use of an intravenous catheter is recommended. Do not use in pregnant animals.

Large animals

Intravenous : 4.0 - 6.0 ml / 50 kg body weight, corresponding to 16-24 mg embutramide, 4-6 mg mebezonium iodide and 0.4-0.6 mg tetracain hydrochloride per KG body weight. To be injected uninterruptedly but not too rapidly (so as to prevent excitation by tetracain).

Dogs

Intravenous:

0.3 ml of product per kg body weight corresponding to 60 mg embutramide, 15 mg mebezonium iodide and 1.5 mg tetracain hydrochloride per KG body weight. To be injected uninterruptedly but not too rapidly (so as to prevent excitation by tetracain). The final third may be injected faster.

Up to 10 kg body weight:

Inject 7 - 10 ml of product intra-pulmonary, corresponding to 1400-2000 mg embutramide, 350-500 mg mebezonium iodide and 35-50 mg tetracain hydrochloride.

Heavier than 10 kg body weight:

An initial dose of 10 ml product, intra-pulmonary (corresponding to 2000 mg embutramide, 500 mg mebezonium iodide and 50 mg tetracain hydrochloride per KG body weight) followed by a supplement of 3-10 ml of product intra-pulmonary (corresponding to 600-2000 mg embutramide, 150-500 mg mebezonium iodide and 15-50 mg tetracain hydrochloride).

Injection technique: the best suited injection site, in standing or prone-lying dog, is in upper third of the thorax, close behind the rear edge of the scapula; a well-pointed needle, of a length adapted to the size of the animal, is to be pushed obliquely in the direction of the opposite ulnar head.

Cats

Intra -pulmonary:

Kittens a few days old: 1.0 ml of product corresponding to 200 mg embutramide, 50 mg mebezonium iodide and 5 mg tetracain hydrochloride.

Up to 6 months: 3.0 ml of product corresponding to 600 mg embutramide, 150 mg mebezonium iodide and 15 mg tetracain hydrochloride.

Older than 6 months: 5.0 ml of product corresponding to 1000 mg embutramide, 250 mg mebezonium iodide and 25 mg tetracain hydrochloride.

Heavier than 5 kg: 10.0 ml of product corresponding to 2000 mg embutramide, 500 mg mebezonium iodide and 50 mg tetracain hydrochloride.

Injection technique: preferentially in cats lying prone on their belly. Injection is 2-3 cm below the spine in the middle of the thorax; a well-pointed needle of length adapted to

the animal's size is to be pushed forward obliquely, in the direction of the opposite ulnar head.

Mink

Intra-pulmonary: 0.5 to 1 ml of product per individual corresponding to 100 - 200 mg embutramide, 25-50 mg mebezonium iodide and 2.5-5 mg tetracain hydrochloride.

Other animals (Such as pigeons, cage birds. Small laboratory animals):

Intra-pulmonary injection: 0.5 - 2.0 ml of product per animal corresponding to 100-400 mg embutramide, 25-100 mg mebezonium iodide and 2.5-10 mg tetracain hydrochloride, according to the size of the animal.

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

Not applicable.

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

May only be administered by a veterinarian.

3.12 Withdrawal periods

Animals that have been euthanized with this veterinary medicinal products may not be consumed by people or animals.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet-code: QN51AX50

4.2 Pharmacodynamics

This veterinary medicinal product contains three active substances with different pharmacological properties:

- Embutramide is a γ -hydroxybutyric acid; it is a strong narcotic and, in high doses, causes an inhibition of the vegetative nerve system, particularly in the respiratory and circulatory centers.
- Mebezonium iodide is highly curarizing. This effect is based on the blocking of stimulus transfer from the nerve endings to the striated muscles. This results in relaxation of the skeletal and respiratory muscles.
- Tetracaine hydrochloride is a local anesthetic. It prevents pain upon pulmonary administration. Intravenously, depending on the dose, tetracaine acts as a central stimulant, subsequently as a cardiac depressant, and finally as a central depressant.

After administration of the veterinary medicinal product, death will occur as a result of cerebral depression, collapse, and respiratory paralysis.

4.3 Pharmacokinetics

Exact details on the pharmacokinetics in target species are not available. The effects of the veterinary medicinal product occur within a few seconds, up to a few minutes.

Under unfavorable absorption conditions, peripheral effects may precede central effects, causing paralysis of the respiratory muscles to precede unconsciousness. Therefore, the veterinary medicinal product should only be used in unconscious (anesthetized) animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

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

The expiry date of the product is indicated on the external packaging.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store below 25°C.

Must be kept locked, out of the reach and sight of children.

5.4 Nature and composition of immediate packaging

Vial of amber glass (type II), 50 ml size, closed with butyl rubber stopper and aluminium seal cap.

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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of as toxic waste, do not throw to sewer.

6. MANUFACTURER

Intervet International GmbH
Feldstrasse 1A 85716
Unterschleissheim
Germany

7. MARKETING AUTHORISATION NUMBER

083-01-92344-01

8. MARKETING AUTHORISATION HOLDER

Intervet Israel Ltd.
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