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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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

For euthanasia of dogs, cats and other animals.

4.3 Contraindications

Do not inject into pleural cavity.
Apply to unconscious animals only.
Do not apply to gestating animals.

4.4 Special warnings per species

None

4.5 Special precautions for use

Special precautions for use in animals

To be applied by veterinarians only.
Apply T61 unconscious (anesthetized) animals only. This is to prevent animals from living though suffocation when conditions of absorption are adverse.
In using T61, 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.

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

This veterinary drug is highly poisonous! Lock away in safe place.
Prevent direct contact with T61.
Immediately remove contaminated clothing.
In case of direct contact of T61 with an open wound, mucous membrane or skin, immediately wash the affected area thoroughly with water and soup and rinse well.
If T61 enters the eye, at once flush them for several minutes, keeping the, open, with clear running water.
In case of accidental pricking, immediately squeeze out the affected area and wash the lesion with abundant water and soup.
Following an intramuscular injection, tie off the extremity concerned, squeeze out the site of the prick.
In case of accidental injection or pricking seek medical advice at once, and show the physician the package insert or label.

Antidotes

If T61 has entered the circulation by being absorbed from wounds or after injection:
Cardio-pulmonary reanimation, administration of atropine and neostigmine, followed by protective hepatic therapy with N-acetylcysteine and haemodialysis if needed.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, convulsions or excitations have been reported. Cardiac failure can occur as an after-effect.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

4.7 Use during pregnancy, lactation or lay

Do not apply to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None, as far as known.

4.9 Dosage and rout of administration

Intravenous, intra-pulmonary.
To be applied by veterinarian only.
T61 must be applied to animals under anesthesia. This is in order to prevent the animal from undergoing live suffocation should the T61 be applied incorrectly or not be properly absorbed.
In using T61, 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.

Havier 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.

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

Not applicable.

4.11 Withdrawal period(s)

Animals which are euthanized by T61 may not be consumed by humans or animals.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Euthanizing agents
ATC vet code: QN51AX50 (combination products)

5.1 Pharmacodynamic properties

T61 contains three active components possessing specific pharmacological characteristics:

- Embutramide is a derivate of γ-hydroxybutyric acid. It is a strong narcotic and causes at high dose an inhibition of the vegetative nervous system, principally at the level of the respiratory and circulatory centers.
- Mebezonium iodide has a strong curare effect. This effect is based upon blocking of the transfer of stimulus from the nerve endings to the striated muscles.
- Tetracaine hydrochloride is a local anesthetic. It prevents pain upon pulmonary administering. By the intravenous rout, Tetracaine acts dose-dependently: first central-stimulating, than cardiac-depressant, and finally central depressant.

After administration of the product, death occurs as a cerebral depression, collapse and asphyxia.

5.2 Pharmacokinetic properties

Precise data on the pharmacokinetics in target animals are not available. The effects of the product arise with a time lag ranging from second to a few minutes.
In unfavorable conditions of absorption the peripheral effects can arise earlier than the central ones, such that paralysis of respiratory muscles precedes unconsciousness. Therefore the use of the veterinary drug must be restricted to unconscious (anesthetized) animals.
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6. PHARMACEUTICAL DATA

6.1 List of excipients

Dimethylformamide
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary drug.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.

The expiry date of the product is indicated on the external packaging.

Shelf-life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

Store below 25°C

6.5 Nature and composition of immediate packaging

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

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 as toxic waste, do not throw to sewer.

7. MANIFACTURER

Intervet International GmbH
Feldstrasse 1a D-85716
Unterschleissheim
Germany

8. MARKETING AUTHORISATION NUMBER

083-01-92344-01

9. MARKETING AUTHORISATION HOLDER

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