

Product information

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BENZOAK VET

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:

Benzocaine (ethyl 4-aminobenzoate) 200.00mg

Excipient(s):

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Stock solution.

4. CLINICAL PARTICULARS

4.1 Target species

Salmon and trout.

4.2 Indications for use, specifying the target species

Anesthesia and sedation of salmon and trout.

4.3 Contraindications

Avoid deep anesthesia of young salmon during the final smolting period.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals:

During anesthesia, the fish must be closely monitored. It is recommended to test a few fish before general application.

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

Do not drink. Harmful if swallowed. In case of ingestion, induce vomiting. Activated charcoal can be administered immediately. Avoid contact with eyes. In case of contact with eyes, immediately flush eyes with plenty of water for at least 15 minutes. Avoid contact with skin and clothing. Direct contact with skin can provoke local anesthesia. Prolonged exposure may cause dermatitis. Operator must wear gloves to prepare and handle the stock and final anesthetic bath. Wash hands thoroughly after handling. Do not eat, drink or smoke when handling the preparation. Keep the stock solution in a tightly closed container and keep out of range of children.

In extremely rare cases, any form of benzocaine may cause methemoglobinemia in hypersensitive persons by contact with skin or mucosa. Cyanosis, neurological and cardiac dysfunction may result when methemoglobin concentration exceeds 30 percent. Clinical diagnosis is made on the presentation of cyanosis unresponsive to oxygen administration and a distinctive arterial blood brown color. Laboratory confirmation is by co-oximetry. Treatment of symptomatic methemoglobinemia is by intravenous methylene blue (1-2mg/kg) administration. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

4.8 Interaction with other medicinal products and other forms of interaction

None interactions described in fish.

4.9 Amounts to be administered and administration route

Stock solution to be dissolved in water. Depending on the desired depth of anesthesia, dilute 15ml to 20ml per 100L of water. Keep water well oxygenated before exposure. The immobilization is produced normally within a few minutes of immersion.

In general, control the total exposure time of the fish in the solution, as there are different levels of tolerance among species of fish and rearing conditions. Maximum exposure time must not exceed 15 minutes.

Transfer anesthetized fish into clear well-oxygenated water for recovery.

Do not feed the fish during at least 48 hours before anesthesia.

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

High concentration or prolonged exposure time may cause medullary collapse, cardiac arrest and death.

Emergency procedure: In case of overdose, transfer the fish immediately in clear flowing water well oxygenated, and make sure the mouth and gills are open.

Antidote: none available.

4.11 Withdrawal period

Seven degrees days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anesthetics, general, other general anesthetics.

ATCVet code: QN01A X92.

5.1 Pharmacodynamic particulars

Benzocaine inhibits the conduction of nerve impulse by blocking the sodium channels. Cationic movements across the membranes are decreased or even abolished. Rest potential remain stable, but action potentials are decreased, as a function of the concentration of the active substance around the nerve fiber. As long as the fish remains in the anesthetic bath (30-40mg/l), the absorption continues until lethal level.

In Salmonidae, deep anesthesia occurs at concentration 9 to 14mg benzocaine per kg body weight. The induction time before optimal anesthesia varies with the rearing conditions, the concentration of the anesthetic bath, and the water temperature.

A normal time range to anesthetize Salmonidae, at temperatures between 10C° and 15C°, and at a concentration of 30 to 40mg/l of active substance (15-20ml Benzoak/100liters), would be 2 to 5 minutes.

Increasing concentration of the active substance results in shorter anesthetic induction times. At the same concentration of benzocaine, the anesthetic induction time decreases with an increase in water temperature.

5.2 Pharmacokinetic particulars

Absorption: Mainly across the gills. Tissue distribution: after absorption across the gills, benzocaine concentrate in the plasma and reach the central nervous system rapidly. After 2 minutes, the plasma concentration of benzocaine is variable. Biotransformation: benzocaine is metabolized by acetylation and deethylation. Elimination: Benzocaine and its acetylated metabolites are rapidly eliminated across the gills. Polar metabolites, like the polar deethylated metabolites are excreted at slower rates in the urine. Benzocaine is rapidly eliminated from plasma within the first 20 minutes after dosing. The plasma concentration decreases rapidly the first 10 minutes. Thereafter, plasma concentration decrease slower with a half-life of 89 to 109 minutes.

In a study with C14-traced benzocaine, brachial elimination accounted for 59.2% of the dose during the first 3 hours. The kidney excreted 2.7% of the dose after 3 hours, and 9.0% after 24 hours. 2.0% of the dose was excreted across the gallbladder after 24 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethylformamide 0,2ml.

Propylene glycol q.s. ad 1ml.

Patent blue (E131) 0,008mg/ml.

6.2 Incompatibilities

None known.

6.3 Shelf-life

Sealed container: 24 months.

Anesthetic bath ready for use: 24 hours.

6.4 Special precautions for storage

Store in the original container and keep the container tightly closed.

Store at room temperature not above 25C°.

Do not freeze.

Protect against light.

Keep out of reach of children.

6.5 Nature and composition of immediate packaging

1-Liter polyethylene (HDPE) bottle with incorporated 20ml dozer. Bottle with one neck. Polypropylene tamper evident caps with gasket. EVA plug separating the dozer chamber and the main bottle chamber. Dozer chamber is graded from 5ml to 15ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not reuse empty bottles.

Any unused veterinary medicinal product should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

97-4919

9. DATE OF FIRST AUTHORISATION

29.06.2000

10. DATE OF REVISION OF THE TEXT

09.02.2016

