SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AQUACEN BENZOCAÍNA 200 mg/ml, concentrado para solución para baño (ES)
AQUACEN BENZOCAÍNA 200 mg/ml, concentrado para solução para banho medicamentoso (PT)
AQUACEN BENZOCAINE 200 mg/ml, Πυκνό διάλυμα για παρασκευή διαλύματος προς εμβάπτιση (EL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Benzocaine ..... 200 mg

Excipients:
Patent blue V (E-131)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dip solution.
Clear and blue solution.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon and trout.

4.2 Indications for use, specifying target species

Anaesthesia and sedation of salmon and trout.
The product is not for use in open water and should always be used in an isolated treatment vessel.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance.
Deep anesthesia of fry has to be avoided during the last stage of smoltification period.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

This veterinary medicinal product does not contain any antimicrobial preservative.

Special precautions for use in animals:

During anaesthesia, the fish must be closely monitored. A number of factors influence the efficacy and safety of the product, including concentration of the drug in water, duration of exposure, temperature, oxygen and density of biomass. Hence it is recommended to test the selected drug con-centration and exposure time is conducted with a small group of representative fish before large numbers are medicated, particularly when water temperature is at the upper or lower ends of the normal temperature ranges for the species being treated. The product should be dissolved in water of the same composition and characteristics as that to which the fish are accustomed.
To minimise damage and loss when medicated the level of sedation should allow fish to maintain their equilibrium and swimming position.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to benzocaine and other para-aminobenzoic acid (PABA) derivatives should avoid contact with the veterinary medicinal product.
In some cases (rare), benzocaine may induce methemoglobinemia in sensitive individuals upon contact with skin or mucous membranes. Cyanosis, neurological or heart (circulation) dysfunctions can occur if the methemoglobin concentration exceeds 30%. The patient with cyanosis doesn't respond to oxygen therapy and has brown arterial blood. The treatment of the signs of methaemoglobinaemia is by intravenous administration of methylene blue (1 - 2 mg/kg).
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. Wash hands after use.
In case of accidental ingestion, induce vomiting and administer activated carbon immediately.
In case of accidental contact with eyes, flush immediately with plenty of water for at least 15 minutes.
Accidental contact with skin or clothing may cause local anesthesia and, prolongued skin exposure can cause dermatitis.
In case of suspected poisoning, seek medicinal advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink while handling the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dipping use

Dissolve 15-20 ml of AQUACEN BENZOCAINE 200 mg/ml per 100 liters of water (equivalent to 30-40 mg of benzocaine per 1 liter of water) depending upon the desired depth of anesthesia.

A good oxygenation of the anesthetic dip has to be maintained during treatment. General anesthesia of the animals is reached within minutes of starting treatment. The total exposure time must be carefully controlled due to the differences between species and their ranges of tolerance. The maximum exposure should not exceed 15 minutes.

The anesthetized fish should be transferred to clean and well oxygenate water to wake up. Fish should not be fed during the last 48 hours before anesthesia.

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

Paralysis of the medulla, cardiac arrest or death can occurs when anesthetic concentration is too high or the exposure time is too long.
Fish should be transferred to fresh and well oxygenated water after the treatment and should be ensured the opening of mouth and gills.
There is no available antidote.

4.11 Withdrawal period(s)

7 degree-days.
Do not use during stripping of fish eggs intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anesthetics, benzocaine.
ATC Vet Code: QN01AX92

5.1 Pharmacodynamic properties

Benzocaine is an anesthetic product commonly used to inhibit the transmission of nerve impulses by blocking sodium channels (Na^+). Cation transport through the membrane decreases or ceases. Resting potential remains stable while the action potential decreases as a function of the concentration of active substance around the nerve fibres. Chronic exposure to anesthetic dip (30-40 mg of benzocaine/l) can lead to lethal levels of absorption.

Deep anesthesia, in salmonids, is achieved with a dose of 9-14 mg of benzocaine per kg body weight.

The time required to reach optimal anesthesia depends on fish size, operating conditions, concentration of anesthetic dip and water temperature. Anesthesia is usually

achieved after 2-5 minutes at temperatures between 10 and 15ºC and at benzocaine concentration of 30-40 mg/l (15-20 ml of AQUACEN BENZOCAINE 200 mg/ml per 100 l). An increasing of temperature or of active substance concentration in the anesthetic dip results in a shorter time for induction of anesthesia.

5.2 Pharmacokinetic particulars

Fish absorb benzocaine mainly through the gills. After the absorption, benzocaine rapidly reaches the plasma and it is distributed throughout the central nervous system. Plasma concentrations after two minutes are variable.

Metabolism is by acetylation and demethylation. Acetylated metabolites are rapidly eliminated through the gills while polar metabolites are slowly excreted in the form of diethyl ether through the urine.

Most of plasma benzocaine is eliminated after 20 minutes of administration. During the first 10 minutes, the elimination is very fast and then disappears slowly with a plasma half-life of 89-109 minutes.

A study with ^{14}C-labeled benzocaine, shows that the 59.2% of the administered dose is excreted through gills for 3 hours. Excretion via kidney is 2.7% after 3 hours and 9.0% after 24 hours. 2.0% of the dose is excreted via bile after 24 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent blue V (E-131)
Dimethyl sulfoxide
Propylene glycol

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 9 months
Shelf life after dilution according the directions: 24 hours

6.4. Special precautions for storage

This veterinary medicinal product does not require special storage conditions.

6.5 Nature and contents of immediate packaging

1 l clear bottles and 5 l white barrels of high density polyethylene.

1 l bottles have an extraction tube and a measuring device. Bottles are closed with screw caps with polyethylene seal with foamed polyethylene shutter disc.
5 l barrels are closed with a polyethylene screw cap and disc for thermo induction.

Package sizes:
Bottle of 1 l
Barrel of 5 l

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

This product is dangerous to fish and other aquatic organisms in the concentrated form. Do not contaminate ponds, streams, lochs or inlets with product or used packaging.

Used solution must be filtered using activated carbon filters and transferred to a holding tank with subsequent controlled release for dilution in the effluent to be discharged from the farm.

Filtration
Filtration of used solution through an activated carbon filter will reduce the concentration of benzocaine in discharge water to values well below 40 ppm.
However, the limit of 1ppb is not achieved with this measure alone so it is necessary to transfer the residual water to a holding tank for dilution in the effluent to be discharged from the farm. The same dilution will be valid considering the worst case that activated carbon does not retain benzocaine or that residual water is eliminated without filtration.
Spent carbon filters should be disposed of in accordance with local requirements.

Holding tank
Transfer filtered solution to a holding tank and controlled release for dilution in the effluent will ensure that the concentration of benzocaine in discharge water does not exceed the trigger of 1 µg/L to safeguard environmental good water quality, when releasing the solution from the holding tank at flow rates calculated in the table below.

GENERAL FARM FLOW (L/min)	OUTFLOW HOLDING TANK (ml/min)
10,000 – 14,999	245
15,000 – 19,999	367
20,000 – 24,999	490
25,000 – 29,999	612
30,000 – 35,000	735

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

CENAVISA, S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)

8. MARKETING AUTHORIZATION NUMBER(S)

9. DATE OF FIRST AUTHORIZATION OR DATE OF RENEWAL OF AUTHORIZATION

DD/MM/YYYY

10. DATE OF REVISION OF THE TEXT

MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensing conditions: **Subject to veterinary prescription.**
Administration conditions: **To be administered by a veterinary surgeon or under their direct responsibility.**