1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Optomease Vet 200 mg/ml concentrate for solution for fish treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Benzocaine 200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent Blue V (E131)	0.008 mg
Dimethyl sulfoxide	
Propylene glycol	

Clear, blue solution..

3. CLINICAL INFORMATION

3.1 Target species

Atlantic Salmon and Rainbow Trout

3.2 Indications for use for each target species

For the anaesthesia and sedation of salmon and trout.
The veterinary medicinal product is not for use in open water and should always be used in an isolated treatment vessel.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

During anaesthesia, the fish must be closely monitored. A number of factors influence the efficacy and safety of the veterinary medicinal 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 concentration 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 veterinary medicinal 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:

Benzocaine may cause hypersensitivity (allergy) following ingestion or contact with the skin or mucosa. In rare cases, benzocaine may cause methaemoglobinaemia (excessive methaemoglobin in the blood) in people who are hypersensitive. Cyanosis (blue skin or lips) may occur as a result of excessive methaemoglobin concentrations.
People with known hypersensitivity to benzocaine or who have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.
Foetal deaths may occur following administration of benzocaine in human beings. Pregnant women should be extra careful to avoid exposure if handling the veterinary medicinal product.
As an anaesthetic, benzocaine may cause adverse reactions, including nervous, respiratory and cardiovascular alterations. This includes direct contact with skin, which can cause local anaesthesia, and prolonged exposure may cause dermatitis.
This veterinary medicinal product also contains DMSO as an excipient, which may be irritant to the skin. Avoid contact with the eyes, skin and clothing.

Personal protective equipment consisting of impermeable gloves should always be worn when handling the veterinary medicinal product and preparing stock solution or the anaesthetic bath.
Do not eat, drink or smoke when handling the veterinary medicinal product or the anaesthetic bath.
In case of contact with the eyes, flush immediately with plenty of clean water. In case of skin contact, wash the exposed area immediately with plenty of water. Remove contaminated clothes immediately. If you develop symptoms following exposure, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Vomiting may be induced; activated charcoal may be administered.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:

In order to protect the environment, used solution must be transferred to a holding tank filled with water with subsequent controlled release for dilution in the effluent to be discharged from the facility. See section 5.5.

3.6 Adverse events

Atlantic Salmon and Rainbow Trout

None known.

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 for breeder fish. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

Water-borne use
The veterinary medicinal product is designed to be dissolved in water. Depending on the desired level of anaesthesia, dilute 15 – 20ml per 100 litres of water of the veterinary medicinal product (equivalent to 30-40 mg of benzocaine per litre of water).
Keep the water well oxygenated before exposure of the fish; immobilisation usually occurs within a few minutes of immersion.
The maximum exposure time must not exceed 15 minutes. In general, the total exposure time of the fish to the solution should be controlled as there are different levels of tolerance among species and rearing conditions.
For recovery, transfer the anaesthetised fish into clear, well oxygenated water. Do not feed the fish for at least 48 hours prior to anaesthesia.

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

In case of overdose, immediately transfer the fish to clear, well oxygenated flowing water and make sure the mouth and gills are open.
High concentrations or prolonged exposure may cause medullary collapse, cardiac arrest and death. No antidote is available.

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

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code: QN01AX92

4.2 Pharmacodynamics

Benzocaine inhibits the conduction of nerve impulses by blocking the sodium channels. Cationic movements across the membranes are decreased or even abolished. Resting potential remains stable, but action potentials are decreased as a function of the concentration of the active substance around the nerve fibre. As long as the fish remains in the anaesthetic bath (30-40 mg/l), the absorption continues until a lethal level is reached.
In Salmonidae, deep anaesthesia occurs at concentrations of 9 – 14 mg benzocaine per kg body weight. The induction time before optimal anaesthesia varies with the rearing conditions, concentration of the anaesthetic bath and the water temperature.
A normal time period to anaesthetise Salmonidae at a temperature of 10 – 15°C and at a concentration of 30 – 40mg/l benzocaine (15 – 20ml Optomease Vet/100 litres water), would be 2 – 5 minutes.
Increasing the concentration of the active substance results in a shorter anaesthetic induction time. At the same concentration of benzocaine, the anaesthetic induction time decreases with an increase in water temperature.

4.3 Pharmacokinetics

Absorption: Mainly across the gills

Tissue Distribution: After absorption, benzocaine concentrates in the plasma and rapidly reaches the central nervous system. After 2 minutes exposure, the plasma concentration of benzocaine is variable.

Biotransformation: Benzocaine is metabolised by acetylation and de-ethylation.

Elimination: Benzocaine and its acetylated metabolites are rapidly eliminated across the gills. Polar metabolites, such as polar de-ethylated 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 within the first 10 minutes. Thereafter, the plasma concentration decreases at a slower rate with a half-life of 89 – 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.

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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after dilution according to directions: use immediately.

5.3 Special precautions for storage

Do not freeze
Store in the original container.
Keep the container tightly closed.
Protect from light.

5.4 Nature and composition of immediate packaging

High-density polyethylene (HDPE) bottle incorporating a low-density polyethylene (LDPE) stopper, with a HDPE outer and polypropylene (PP) inner child resistant cap. The 125ml bottle is fitted with an integral 10ml measuring device, and the 1000ml bottle is fitted with an integral 25ml measuring device.

Package sizes:
Bottle of 125 ml with an integral 10 ml measuring device
Bottle of 1000 ml with an integral 25 ml measuring device

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.

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Do not contaminate ponds, streams, lochs or inlets with veterinary medicinal product or used packaging. Used solution must be transferred to a holding tank filled with water with subsequent controlled release for dilution in the effluent to be discharged from the facility. The use of the veterinary medicinal product is limited to facilities equipped with suitable technology to guarantee safe discharges as indicated below. Transfer of used solution to a holding tank filled with water and controlled release for dilution in effluent will ensure that the concentration of spent benzocaine in discharge water does not exceed 1 µg/L.

Dilution in effluent must ensure that the concentration of spent benzocaine in discharge water does not exceed the trigger of 1 µg/L safeguarding environmentally good water quality.
When releasing the solution from the holding tank, flow rates are calculated based on the following equation:

$$\text{Discharge (L/hr)} = \frac{\text{Farm flow rate (L/min)} \times 0.90 \text{ (safety factor)}}{\text{concentration (mg/L)} \times 1000} \text{ Holding tank} \times 60$$

Eg. Holding tank concentration (mg/L)	**Farm flow rate (L/min)**	**Discharge flow from holding tank (L/h)**
5	10,000 / 20,000 / 30,000	108 / 216 / 324
10	10,000 / 20,000 / 30,000	54 / 108 / 162
20	10,000 / 20,000 / 30,000	27 / 54 / 81
40	10,000 / 20,000 / 30,000	14 / 27 / 41

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/114/001

8. DATE OF FIRST AUTHORISATION

12/06/2020

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

19/12/2025

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).