ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Optomease Vet 200mg/ml concentrate for solution for fish treatment (UK, NO, DK, IE)

Optomease 200mg/ml concentrate for solution for fish treatment (ES, EL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Benzocaine 200mg

Excipients:

Patent Blue V (E131) 0.008 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for fish treatment.

The solution is a clear, blue liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic Salmon and Rainbow Trout

4.2 Indications for use, specifying the target species

For the 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

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i 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 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 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.

ii 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.

Avoid handling this product if you know you are sensitised to benzocaine, or if you have been advised not to work with such preparations.

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.

Do not eat, drink or smoke when handling the product or the anaesthetic bath.

Always wear impermeable gloves when handling the product and preparing stock solution 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, you should seek medical advice and show the package leaflet or the label to the doctor.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet / label to the doctor. Vomiting may be induced; activated charcoal may be administered.

Foetal deaths may occur following administration of benzocaine in human beings.

Pregnant women should be extra careful to avoid exposure if handling the product.

Wash hands thoroughly after use.

iii Other precautions

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 6.6.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

No data available

4.9 Amounts to be administered and administration route

The 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; immobilization 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 anaesthetized fish into clear, well oxygenated water.

Do not feed the fish for at least 48 hours prior to anaesthesia.

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

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.

4.11 Withdrawal period(s)

Meat: 7 degree days

Do not use during stripping of fish eggs intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QN01A X92
Anaesthetics, general, other general anaesthetics.

5.1 Pharmacodynamic properties

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 (30-40mg/l), the absorption continues until a lethal level is reached.

In Salmonidae, deep anaesthesia occurs at concentrations of 9 – 14mg 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulfoxide (DMSO)
Propylene Glycol
Patent Blue V (E131)

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: Use immediately.
Shelf life after dilution according to directions: Use immediately.

6.4. Special precautions for storage

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

6.5 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 doser, and the 1000ml bottle is fitted with an integral 25ml doser

Package size:
Single Neck Dispenser Bottle of 125ml with an integral 10ml doser and cap
Single or Double Neck Dispenser Bottle of 1000ml with an integral 25ml doser and with one or two caps respectively

Not all pack sizes may be marketed

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

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 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 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:

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

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

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

7. MARKETING AUTHORISATION HOLDER

Virbac S.A.
1 ére avenue 2065 m - LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER(S)

to be completed Nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th March 2020

10 DATE OF REVISION OF THE TEXT