LABELLING AND PACKAGE LEAFLET

COMBINED LABEL AND PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer for the batch release:

CENAVISA, S.L.
Camí Pedra Estela s/n
43205 REUS (SPAIN)
Tel. 34 977 757 273
www.cenavisa.com / e-mail: cenavisa@cenavisa.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Benzocaine ..... 200 mg

Excipients, q.s.
Patent blue V (E-131)

Clear and blue solution.

4. PHARMACEUTICAL FORM

Concentrate for dip emulsion

5. PACKAGE SIZE

1 l
5 l

6. INDICATIONS

Anesthesia 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.

7. 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 moltification period.

8. ADVERSE REACTIONS

Not known.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Atlantic salmon and trout.

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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.

11. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

12. WITHDRAWAL PERIOD

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

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

14. SPECIAL WARNINGS

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, tem-perature, 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.
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Special precautions to be taken by the person administering the medicinal product to the 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.

Overdose:
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.

Incompatibilities:

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

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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 1 µg/L 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 products should be disposed of in accordance with local requirements.

16. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

17. OTHER INFORMATION

Pack size: 1 l bottle
5 l barrel
Not all pack sizes may be marketed.

To be administered by a veterinary surgeon or under their direct responsibility.

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLU AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

20. EXPIRY DATE

EXP {month/year}

Once opened use by…

Shelf life after first opening the container: 9 months
Shelf life after dilution according to directions: 24 hours

21. MARKETING AUTHORISATION NUMBER(S)

22. MANUFACTURER’S BATCH NUMBER

Batch {number}