PACKAGE LEAFLET:

Salmosan Vet, 500 mg/g powder for suspension for fish treatment.

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

Marketing authorisation holder:

Benchmark Animal Health Limited
Highdown House
Yeoman Way
Worthing
West Sussex
BN99 3HH
United Kingdom

Manufacturer responsible for batch release:

Animax Limited, Shepherds Grove West, Stanton, Bury St Edmunds, Suffolk IP31 2AR, UK

or

Freja Transport og Logistics A/S, Litauen Alle 6, Taastrup, 2630 Denmark

or

Freja Transport and Logistics AS Fjellbovegen 13 Frogner, 2016 Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan Vet, 500 mg/g powder for suspension for fish treatment
Azamethiphos

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active Substance: Azamethiphos 500 mg/g

Excipients: Sodium Laurilsulfate and silicic acid are present as wetting and dispersing agents

Powder for suspension in water for the treatment of fish by means of the bath technique.

Light beige to beige powder

4. INDICATION(S)

For treatment of pre-adult to adult sea-lice (*Lepeophtheirus salmonis* or *Caligus* species) on farmed Atlantic salmon.

5. CONTRAINDICATIONS

Do not use the product in cases of known hypersensitivity to the active substance or any of the excipients.

6. ADVERSE REACTIONS

Signs of hyperactivity or distress may be seen if fish are not adequately oxygenated during treatment.

Mortalities of treated fish is uncommonly observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to <the marketing authorisation holder><the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system

National contact details: https://www.gov.uk/report-veterinary-medicine-problem

7. TARGET SPECIES

Farmed Atlantic salmon (*Salmo salar*)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

READ THE OPERATOR PRECAUTIONS AND ENVIRONMENTAL WARNINGS.

The prescribing veterinary surgeon or fish health biologist (Norway) must ensure that farm staff have received adequate instruction in the safe use of Salmosan Vet.

Fish affected by sea-lice should be bathed in 0.2 ppm Salmosan Vet (0.1 ppm azamethiphos) for a period of not less than 30 minutes and not more than 60 minutes.

Assess treatment water volume as accurately as possible when calculating the amount of product needed for treatment to avoid under or overdosing.

Oxygenation must be provided during treatment, ideally continuously while the fish are crowded in the net and the tarpaulin is fitted to and removed from the cage. Vigorous oxygenation is recommended in the treatment cage. Where several cages are to be treated a large reservoir of oxygen bottles should be available.

To achieve a final concentration of 0.1 ppm azamethiphos, 0.2 g of Salmosan Vet must be added per cubic metre of water, i.e., 1 x 100 g sachet treats 500 cubic metres.

Initial preparation of the treatment concentrate should take place in a dry and sheltered location, not more than 48 hours prior to treatment. Operators wearing suitable equipment and protective clothing should place the number of water soluble bags of Salmosan® Vet required for the dosage of an individual cage into a labelled screw-topped polyethylene container, together with a quantity of fresh water (1 litre or more of water for every 200 g of Salmosan Vet). Screw the lid tightly onto the container and gently shake this initial dilution for up to 5 minutes.

When fish are ready to be treated, the diluted suspension of Salmosan Vet should be further diluted into approximately 200 to 1000 litres of sea water and gently stirred for 5 minutes. The polyethylene container, in which the first dilution was prepared, should be rinsed with sea water and the rinsing from this should be added to the sea water dilution tank. This latter mixture should then be immediately and carefully added to the cage by pouring or pumping the mixture into the water as evenly and efficiently as possible using the Bath Technique.

9. ADVICE ON CORRECT ADMINISTRATION

almosan Vet should be applied to salmon suffering from infestation with pre-adult to adult sea-lice (*Lepeophtheirus salmonis* or *Caligus* species) before the stage at which serious skin damage is evident.

THE BATH TECHNIQUE

In this technique, the depth of the fish cage net is reduced to a known depth at the centre and a tarpaulin placed around the net so that it is totally enclosed. Ensure the base of the cage is not drooping when in the raised position as fish may congregate and come to harm. The volume of water to be treated should be estimated as accurately as possible, restrictive tarpaulins can be used to give a better management of water volume and reduce the amount of product needed depending on biomass of fish to be treated. Oxygenation should begin before the tarpaulin is fitted and continue until the tarpaulin is fully removed after treatment. Once the tarpaulin is in place the product (in the seawater dilution) should be immediately added. When the addition of product diluted in seawater to the tarpaulined cage is completed the treatment time begins. At the end of the treatment time the tarpaulin should be removed as quickly as possible allowing the exchange of clean seawater into the cage. The Bath Technique is designed to ensure the product is used in a totally enclosed volume of water.

10. WITHDRAWAL PERIOD(S)

10 Degree days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Store in the original unopened package.

Store in a dry place.

Store away from food, drink and animal feedingstuff.

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

12. SPECIAL WARNING(S)

Special warnings for each target species:

The product does not treat juvenile attached sea lice which may be present with the pre-adult and adult stages. These juvenile stages will develop into pre-adults and adults in 10 to 20 days when the population count should show whether a second treatment is necessary. All fish on the site should be simultaneously treated.

Resistance is known to occur where incomplete treatments are carried out. To help prevent resistance occurring ensure the correct dose and duration of treatment is accomplished. Only fully enclosed treatments should be used. Repeated use of the same class of chemotherapeutic agent may result in the development of resistance. In order to reduce the risk of resistance to the product developing, the product should be used as part of a rotational strategy in the medicinal treatment of sea lice.

Where there are concerns of decreasing sensitivity of lice to Azamethiphos based products the maximum treatment time (60 minutes) should be used to achieve optimum efficacy and limit the opportunity for resistance development.

Do not use the product prophylactically. Only use when infestation with mature lice has been diagnosed.

Special precautions for use in animals:

For external use only.

Careful management and monitoring of oxygen levels is critical during Salmosan Vet treatments. A minimum oxygen level should be set by the prescriber prior to treatment. In order to maintain oxygen levels, vigorous oxygenation of the water must be provided during treatment. It is recommended that oxygen addition begins before the tarpaulins are fitted to the pens.

Impaired gill health and concurrent diseases such as pancreas disease and cardiomyopathy syndrome has been shown to increase fish mortality post treatment, due to stress related to the treatment and/or treatment procedure.

The product should be applied to salmon suffering from infestations with pre-adult and adult sea lice before the stage at which serious skin damage is evident.

During treatment, fish should be monitored for, but not limited to, signs of stress (lethargy, gasping, orientation problems, balance problems and abnormal swimming behaviour). If any of these signs are observed during or shortly after treatment, flush the treatment area with clean sea water and ensure vigorous oxygenation.

A laboratory study was conducted to determine the safety of treatment at temperatures above 10°C for the maximum recommended treatment duration of 60 minutes. Salmon (with bodyweights from 350 g) appeared to tolerate exposure to Salmosan® Vet at up to three times the recommended dose rate (i.e. 0.6 ppm), for up to three times the recommended treatment time (i.e. 180 minutes), at both 6°C and 15°C.

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

This product contains azamethiphos. Azamethiphos is an organophosphorus compound. DO NOT USE if under medical advice not to work with such compounds.

THIS PRODUCT MAY CAUSE SENSITISATION (ALLERGY) BY SKIN CONTACT OR INHALATION.

AVOID ALL CONTACT WITH MOUTH, SKIN OR EYES.

ACCIDENTAL SPLASHES ON EXPOSED SKIN OR EYES should be washed off immediately with plenty of water.

WEAR SUITABLE PROTECTIVE CLOTHING SUCH AS WATERPROOF COVERALLS, HEAVY DUTY GAUNTLET STYLE NITRILE GLOVES of at least 300 mm length and 0.5 mm thickness, FACE SHIELD AND RESPIRATORY PROTECTION, both when handling the concentrate and when applying the diluted chemical to the pen.

RENEW PROTECTIVE CLOTHING AND EQUIPMENT REGULARLY and certainly when cracking or damage has occurred.

WASH ALL PROTECTIVE CLOTHING thoroughly after use, especially the insides of gloves.

REMOVE HEAVILY CONTAMINATED CLOTHING IMMEDIATELY after a spill; wash or destroy.

Ensure that the drum/container is securely closed during the dissolving process.

DO NOT EAT, DRINK OR SMOKE without first withdrawing from the work area, removing protective clothing and washing hands, face and exposed skin.

WASH HANDS, FACE AND ANY EXPOSED SKIN immediately after leaving the work area.

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.

RINSE APPLICATION EQUIPMENT AND CONTAINERS AFTER USE.

MEDICAL ADVICE TO USERS

- If you have previously felt unwell after using a product containing an organophosphorus compound, consult your doctor before working with this product and show your doctor the product label.
- If you feel unwell after using this product, consult your doctor and show your doctor the product label.
- Treat any cases of heavy contamination as an emergency. You should go straight to hospital after removing contaminated clothing, and rinse areas of skin which came into contact with the product with plenty of water.
- If the product has been swallowed go straight to hospital and take the product label with you.

MEDICAL ADVICE TO DOCTORS

Poisoning from organophosphorus compounds results from blockage of acetylcholinesterase, with a resulting over-activity of acetylcholine.

Symptoms include headache, exhaustion and weakness, mental confusion together with blurred vision, excessive salivation and sweating, cramp-like abdominal pain, chest tightness, diarrhoea, constricted pupils and bronchorrhea. These may develop for up to 24 hours after exposure.

Severe poisoning can include general muscle twitching, loss of coordination, extreme difficulty with breathing and convulsions which may lead to unconsciousness in the absence of medical treatment. Treat symptomatically and seek urgent hospital transfer if poisoning is suspected.

Advice on clinical management is available from the National Poisons Information Service.

<u>Other Precautions</u>

The product is very dangerous to crustaceans and is dangerous to fish and other aquatic organisms; therefore the product should not be used in sea farms where crabs and lobsters are kept in close proximity of the treated cages.

Frequent use and/or use on a larger scale may pose an increased risk to the environment. In order to ensure safe use (including large scale and multiple treatments) of the product under a combination of different environmental conditions (e.g. low water current speeds, shallow waters, short distance to the shore etc.), local environmental regulations governing discharges, where applicable, must be adhered to. **If there is any doubt about safe use in the environment, relevant competent authorities should be consulted or professional advice sought accordingly.**

Azamethiphos is highly soluble in water (>1 g/L) with a low octanol/water partition coefficient (log Kow) of 1.0 g/ml. These characteristics indicate that azamethiphos will remain in the aqueous phase and will not enter the sediments.

Azamethiphos has a moderate propensity to adsorb to suspended organic matter; however it is unstable in salt water, degrading with a half-life of <5.6 days (at 12°C), producing non-toxic transformation products. Hydrolytic degradation is the primary breakdown route but photolysis and microbial action will also hasten the process.

The most important mechanism for removal of the product in coastal waters is dilution which is increased by water movements including the flushing effects in sea lochs. After treatment, care should be taken to provide sufficient water exchange through the net to dilute residual azamethiphos. The water movements from a boat's propeller may be used to increase water exchange in cases where low water exchange rates cannot be avoided. These measures will help to prevent possible adverse effects on aquatic life.

From a practical use position, 'restrictive tarpaulins' are commonly available now and can be used to reduce the volume of larger net pens for bath treatments. Depending on biomass, these tarpaulins can reduce the size of larger pen nets by >60%. This is good practice which not only allows for better measurement of the water volume to be treated but also reduces the amount of product needed to be used and therefore released at the end of treatment.

For countries where an environmental authorisation is not required at each individual site, the following risk mitigation measures should be followed:

At sites with cages ≥ 150 m in circumference, a maximum of one cage should be treated per day.

At sites with cages 120-149 m in circumference, a maximum of two cages should be treated per day.

Pregnancy:

The safety of the product with regard to reproduction toxicity has not been assessed. Therefore, only use in maturing brood stock in accordance with the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

During a study exposing salmon to up to three times the recommended dose rate for up to 180 minutes no adverse events were observed during the treatment period. However, a small percentage of fish showed reversible changes in colour after the 180 minute treatment period and a very small percentage of fish showed an irreversible loss of equilibrium (at doses of two and three times the recommended treatment dose). It is reported that prolonged exposure to azamethiphos at concentrations in excess of 0.1 ppm signs of stress, stupor and in extreme cases death may occur. If acute toxicity is seen the treatment should be stopped, oxygenation increased, and the tarpaulin removed to aid recovery.

Incompatibilities:

None known.

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

The 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.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2023

15. OTHER INFORMATION

Heat-sealed PVA water soluble bags containing 20 g or 100 g of product contained in a sealed polyethylene lined paper sachet.

5 x 20 g or 2 x 100 g sachets in a box.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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