SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan Vet, 500 mg/g Powder for Suspension for Fish Treatment.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Azamethiphos 500 mg

Excipients:

For the full list of excipients see Section 6.1

3. PHARMACEUTICAL FORM

Powder for suspension for fish treatment.
Light beige to beige powder.

4. CLINICAL PARTICULARS

4.1 Target species

Farmed Atlantic salmon (*Salmo salar*)

4.2 Indications for use (specifying the target species)

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

4.3 Contraindications

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

4.4 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 (see also Section 4.5).

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

4.5 Special precautions for use

i. 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.

ii. 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.

iii. Other precautions

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.**

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.

4.6 Adverse reactions (frequency and seriousness)

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 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 also the last section of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

READ THE OPERATOR PRECAUTIONS AND ENVIRONMENTAL WARNINGS (see Sections 4.5.ii and 5.3 of the SPC).

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

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

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

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.

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, (See Section 4.5.ii of the SPC), should place the number of water soluble bags of the product 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 the product). Screw the lid tightly onto the container and gently shake this intial dilution for up to 5 minutes.

When fish are ready to be treated, the diluted suspension of the product 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.

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.

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

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.

4.11 Withdrawal period(s)

Withdrawal period: 10 degree days.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP53AF17

Ectoparasiticides for topical use, organophosphorus compounds.

5.1 Pharmacodynamic properties

Organophosphorus insecticide, acting by anticholinesterase activity. Resistance to azamethiphos and other organophosphates has been demonstrated in some sea-lice populations. Although the mechanism is not fully elucidated, it is probable that resistance is due to a genetic alteration of the enzyme acetylcholinesterase influenced by natural selection.

5.2 Pharmacokinetic properties

Radiolabelled metabolism studies in salmon have shown azamethiphos residues in tissues and organs are depleted quickly and are below the limit of detection 1 hour after immersion for 60 minutes in a bath containing the maximum recommended dose.

5.3 Environmental properties

Azamethiphos is highly soluble in water (>1g/l) with a low octanol/water partition coefficient (log K_{ow}) 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Laurilsulfate
Kaolin Light
Silicic Acid Precipitated

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
3 years

6.4 Special precautions for storage

Do not store above 25ºC.
Store in the original unopened packaging.
Store in a dry place.
Store away from food, drink and animal feedingstuff.

6.5 Nature and composition of immediate packaging

Heat-sealed PVA water soluble bag 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 packages in a box.

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

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.

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 43684/4002

9. DATE OF FIRST AUTHORISATION

10 December 2014

10. DATE OF REVISION OF THE TEXT

December 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

Approved 22 December 2022