

PARTICULARS TO APPEAR ON THE OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan Powder for Suspension for Fish Treatment containing 50% w/w Azamethiphos

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

50% w/w Azamethiphos

3. PHARMACEUTICAL FORM

Powder for Suspension

4. PACKAGE SIZE

5 x 20g or 2 x 100g

5. TARGET SPECIES

Atlantic Salmon

6. INDICATION(S)

For the control of sea lice in farmed salmon

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read all operator precautions, environmental warnings and instructions on enclosure leaflet prior to use.

Contains water soluble bag.

8. WITHDRAWAL PERIOD

24 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read all operator precautions, environmental warnings and instructions on enclosure leaflet prior to use.

May cause sensitisation by inhalation and skin contact

Harmful symbol

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25°C

Store in the original unopened packaging

Store in a dry place

Store away from food, drink and animal feedingstuff

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read all operator precautions, environmental warnings and instructions on enclosure leaflet prior to use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V

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

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Fish Vet Group Ltd. 22 Carsegate Road, Inverness, IV3 8EX. Scotland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 33459/4000

17. MANUFACTURER’S BATCH NUMBER

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Water soluble bag}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 50 % w/w azamethiphos

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 or 100 g

4. INDICATIONS

For the control of sea lice on farmed salmon

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

Fish Vet Group Ltd. 22 Carsegate Road, Inverness, IV3 8EX. Scotland

PARTICULARS TO APPEAR ON THE OUTER SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan Powder for Suspension for Fish Treatment containing 50% w/w Azamethiphos

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

50% w/w Azamethiphos

3. PHARMACEUTICAL FORM

Powder for Suspension

4. PACKAGE SIZE

5. TARGET SPECIES

Atlantic Salmon

6. INDICATION(S)

For the control of sea lice in farmed salmon

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read all operator precautions, environmental warnings and instructions on enclosure leaflet prior to use.

Contains water soluble bag.

Salmosan is contained inside this sachet in a water soluble bag. The water soluble bag should be dropped straight into the mixer bottle. Do not touch the water soluble bag with wet gloves. Do not open water soluble bag.

8. WITHDRAWAL PERIOD

24 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read all operator precautions, environmental warnings and instructions on enclosure leaflet prior to use.

May cause sensitisation by inhalation and skin contact

Harmful symbol

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25°C

Store in the original unopened packaging

Store in a dry place

Store away from food, drink and animal feedingstuff

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read all operator precautions, environmental warnings and instructions on enclosure leaflet prior to use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V

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

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

KEEP OUT OF REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Fish Vet Group Ltd. 22 Carsegate Road, Inverness, IV3 8EX. Scotland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 33459/4000

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

Fish Vet Group Limited
22 Carsegate Road
Inverness
IV3 8EX
Scotland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan Powder for Suspension for Fish Treatment containing 50% w/w Azamethiphos

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

A wettable powder containing 50% w/w azamethiphos for dilution in water and subsequent administration by The Bath Technique.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Atlantic Salmon

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

READ THE OPERATOR PRECAUTIONS AND ENVIRONMENTAL WARNINGS. The prescribing veterinary surgeon must ensure that farm staff have received adequate instruction in the safe use of Salmosan.

Salmosan should be applied to salmon suffering from infestation with mature (pre-adult to adult) sea-lice (*Lepeophtheirus salmonis*) or (*Caligus* species) before the stage at which serious skin damage is evident. The exact timing of a treatment and setting up of a treatment programme is a matter of expertise and judgement; operators must seek the advice of the prescribing veterinary surgeon.

Salmosan does not affect juvenile attached sea-lice which will 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 a population count should show whether a second treatment is necessary. A third treatment may be necessary after another 14 days, after which fish should be lice free for considerable periods, if all fish on the site have been simultaneously treated.

Fish affected by sea-lice should be bathed in 0.2 ppm Salmosan (0.1 ppm azamethiphos) for a period of not less than 30 minutes and not more than 60 minutes. At water temperatures above 10°C it is advisable to limit treatment periods to 30 minutes. Assess water volume as accurately as possible.

During treatment, careful observation of fish behaviour must be maintained. If signs of distress, e.g., fish falling on their side, occur after 30 minutes of treatment, remove tarpaulin and ensure vigorous oxygenation of the water. Oxygenation must be provided during treatment. Vigorous oxygenation is recommended in the treatment cage. Where several cages are to be treated a large reservoir of oxygen bottles should be available.

On dry land, not more than 48 hours prior to treatment, operators wearing suitable equipment and protective clothing, (See OPERATOR WARNINGS), should place the required number of water soluble bags of Salmosan required for the dosage of an individual cage into a labelled screw-topped polyethylene container, together with a quantity of distilled water (1 litre or more of distilled water for every 200g of Salmosan).

To achieve a final concentration of 0.1 ppm azamethiphos, 0.2g of Salmosan powder must be added per cubic metre of water, i.e., 1 x 20g sachet treats 100 cubic metres.

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 should be further diluted into approximately 200 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 next dilution. This latter mixture should then be immediately and carefully added to the cage by pouring or pumping the mixture into the water at the oxygen diffuser points 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, e.g., 2 metres, 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. Oxygen is immediately bled into the system and Salmosan is added. After 30 to 60 minutes the tarpaulin is removed.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Fish for human consumption may be taken only after 24 hours after the end of the treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C

Store in the original unopened packaging

Store in a dry place

Store away from food, drink and animal feedingstuff

12. SPECIAL WARNING(S)

MAY CAUSE SENSITISATION BY INHALATION AND SKIN CONTACT

The Control of Substances Hazardous to Health Regulations 1988 (COSHH) applies to the use of this product at work.

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

WEAR SUITABLE PROTECTIVE CLOTHING (WATERPROOF COVERALLS), SUITABLE PROTECTIVE GLOVES (heavy duty gauntlet style nitrile at least 300mm in length and 0.5mm thick are recommended) AND FACE PROTECTION (FACE SHIELD) when handling the concentrate (i.e., mixing or transferring product from one container to another) and when applying the diluted chemical to the pen. Renew protective clothing and gloves regularly and certainly when cracking or damage has occurred. Initial dilution of the water soluble bags into a small volume of distilled water must be carried out on land, ensure that the drum container is securely closed during this process.

RINSE APPLICATION EQUIPMENT AND CONTAINERS AFTER USE

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

REMOVE HEAVILY CONTAMINATED CLOTHING IMMEDIATELY, wash or destroy. DO NOT EAT, DRINK OR SMOKE without first withdrawing from the work area, removing protective clothing and washing hands, face and exposed skin.

AVOID ALL CONTACT BY MOUTH, WITH THE SKIN OR EYES.

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

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

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.

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 with plenty of water areas of skin which came into contact with the product.

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 resultant 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. (Local information is included on mock ups)

REPORTING INCIDENTS

Illness suspected to be a result of working with Salmosan may be reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985. If in doubt contact your local Health and Safety Executive Officer.

Report human or veterinary suspected adverse reactions to the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS.

Further advice can be obtained from: Fish Vet Group, 22 Caresgate Road, Inverness, IV3 8EX, Scotland. Tel: +44 (0) 1463 717774. For Animal Treatment Only

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

Salmosan is dangerous to many organisms. The fastest and therefore most important detoxification mechanism in coastal waters is dilution which is increased by water movements including the flushing effect in sea lochs.

Do not use Salmosan prophylactically. Only use when infestation with adult lice has been diagnosed.

Salmosan 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.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulations authority.

Do not re-use packaging for any purpose.

Salmosan is a Prescription Only Medicine under the Medicines Act (1968). Use of this product at certain sites with lower water movements may be restricted or prohibited. The user must therefore apply for and obtain discharge consent at each individual site from the Scottish Environment Protection Agency (Environment Agency in England and Wales, Environmental Division of the Department of the Environment for Northern Ireland) prior to the use of this product.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 33549/4000