SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azasure 500 mg/g Powder for Suspension for Fish Treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

1g of product contains azamethiphos 500mg

Excipients:

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Powder for suspension for fish treatment. Fine beige powder in water soluble sachet.

4. CLINICAL PARTICULARS

4.1 Target species

Farmed Atlantic salmon (Salmo salar)

4.2 Indications for use (specifying the target species)

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

4.3 Contraindications

None

4.4 Special warnings (for each target species)

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 multi-tactic pest-management program.
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.
Do not use the product prophylactically. Only use when infestation with adult lice has been diagnosed.

4.5 Special precautions for use

i Special precautions for use in animals

At water temperatures above 10□C it is advisable to limit treatment periods to 30 minutes. Vigorous oxygenation of the water must be provided during treatment.

For external use only.
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 the tarpaulin and ensure vigorous oxygenation of the water.
The product should be applied to salmon suffering from infestation with sea-lice before the stage at which serious skin damage is evident.

ii. Special precautions to be taken by the person administering the medicinal product to animals

The prescribing veterinary surgeon must ensure that farm staff have received adequate instruction in the safe use of the product.

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.
The product 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.

REPORTING INCIDENTS

In the UK

Illness suspected to be a result of working with the medicine may be reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. If in doubt contact your local Health and Safety Executive Officer.

Report human or veterinary suspected adverse reactions online to the Veterinary Medicines Directorate.

In Norway

Adverse reactions, including human reactions, should be reported to the Norwegian Medicines Agency, **www.noma.no**.

Further advice can be obtained from: Naqua Limited, Building 500, East Block, Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND

iii. Other Precautions

The product is very dangerous to crustaceans and dangerous to fish and other aquatic organisms. Therefore the product should not be used in sea farms where crabs or lobsters are kept in the close proximity of the treated sea 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, 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 boats 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.
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 ≥ 150m in circumference a maximum of one cage should be treated per day.
At sites with cages 120 – 149m in circumference, a maximum of two cages should be treated per day.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of nteraction

No data available

4.9 Amount(s) to be administered and administration route

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. At water temperatures above 10□C it is advisable to limit treatment periods to 30 minutes. Assess water volume as accurately as possible.

To achieve a final concentration of 0.1 ppm azamethiphos, 0.2g of the powder must be added per cubic metre of water, i.e., 1 x 20g sachet treats 100 cubic meters and 1 x 100g sachet treats 500 cubic metres.

The product 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.

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 PRECAUTIONS), should place the required 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 distilled water (1 litre or more of distilled water for every 200g of 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 product 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, 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. Oxygen is immediately bled into the system and the product is added. After 30 to 60 minutes the tarpaulin is removed.

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

Azamethiphos induces little change in brain acetylcholinesterases at therapeutic concentrations but some fish may show hyperactivity. At concentrations in excess of 0.1ppm signs of stress, stupor and in extreme cases death may occur. If acute toxicity is seen the treatment should be stopped and oxygenation increased to aid recovery.

4.11 Withdrawal period(s)

Fish for human consumption may be taken only after 10 degree days after the end of the treatment.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP53AF17

Antiparasitic Products, Insecticides and Repellants

5.1 Pharmacodynamic properties

Azamethiphos is an organophosphorus insecticide.
Resistance of sea lice to azamethiphos, and other organophosphates, can occur through alteration of acetylcholinesterase due to genetic mutation influenced by natural selection.

5.2 Pharmacokinetic properties

Radio labelled metabolism studies in salmon have shown azamethiphos residues in tissues and organs are depleted quickly and are below the limit of detection within 1 hour of immersion in a bath containing the maximum recommended dose.

5.3 Environmental properties

Azamethiphos is highly soluble in water (>1 g/L) with a low octanol/water partition coefficient (log Kow) of 1 g/mL. These characteristics indicate that azamethiphos will remain in the aqueous phase and will not bioconcentrate or bioaccumulate in biota. Azamethiphos has a moderate propensity to adsorb to suspended organic matter (koc 500 l/kg), however it is unstable in saltwater, degrading with a half-life <5 days (12 C) producing non-toxic transformation products. See also 4.5.iii.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Laurilsulfate
Kaolin Light
Silica, colloidal anhydrous

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 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

20g pack size;
Heat-sealed polyvinylalcohol water soluble bag containing 20g of product contained in a sealed aluminium/polyethylene sachet.
Either 2 x 20g packages in an outer carton or 5 x 20g packages in an outer carton.

100g pack size;
Heat-sealed polyvinylalcohol water soluble bag containing 100g of product contained in a sealed aluminium/polyethylene sachet.
Either 1 x 100g package in an outer carton or 5 x 100g packages in an outer carton.

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, if appropriate

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.

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

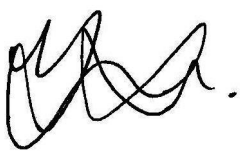
Ground Animal Health Ltd
Unit 8 Dock Offices
Surrey Quays Road
London
England
SE16 2XU

8. MARKETING AUTHORISATION NUMBER

Vm 49145/4000

9. DATE OF FIRST AUTHORISATION

04 December 2013



10. DATE OF REVISION OF THE TEXT

August 2023 Approved: 03 August 2023