PACKAGE LEAFLET:
AMX 10 mg/ml Concentrate for solution 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 and manufacturer responsible for batch release:
PHARMAQ AS
Skogmo Industriområde
N-7863 Overhalla
Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMX 10 mg/ml concentrate for solution for fish treatment
Deltamethrin

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

Active substance: Deltamethrin 10 mg/ml
Excipient: N-methyl pyrrolidone 648 mg/ml

Slightly opaque, pale yellow liquid.

4. INDICATION(S)

For treatment of adult and pre adult sea lice (*Lepeophteirus salmonis*) on Atlantic salmon (*Salmo salar*) and rainbow trout (*Oncorhynchus mykiss).*

5. CONTRAINDICATIONS

Do not use during outbreaks of infectious diseases as treatment against sea lice may aggravate the clinical signs and increase mortality.

6. ADVERSE REACTIONS

The fish tend to move closer to the surface during treatment and increased restlessness and jumping frequency are observed. Occasional mortalities have been observed after treatment with the recommended treatment regimen. Miscalculation of the treatment volume (overdosing), low water temperatures or prolonged exposure may increase the frequency of adverse reactions or signs of intoxication.

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.

7. TARGET SPECIES

Atlantic salmon *(Salmo salar)* and rainbow trout (*Oncorhynchus mykiss).*

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

The delousing should be performed in a well-boat or in a sea-cage with a raised net enclosed by a tarpaulin. This is to ensure proper control of the treatment volume and the treatment dosage, in addition to reduce the amount of AMX used and the environmental exposure. Calculate the water volume as exactly as possible to ensure correct dosing.

Dosage
0.2 ml AMX pr. m^3 (1000 litre) sea water in the treatment unit. This corresponds to 2 microgram deltamethrin/litre sea water. For calculation of the treatment volume in the unit, please refer to the section below; "Treatment volume".

Treatment period: 30 minutes

Treatment volume
Well-boat: The dosage is calculated according to the actual volume of the treatment unit.
Tarpaulin: The dosage is calculated according to the actual volume of the treatment unit (tarpaulin volume).

9. ADVICE ON CORRECT ADMINISTRATION

The product should be brought to room temperature before use in order to flow more easily out of the bottle. Shake the bottle well before use. Calculate the volume of the treatment unit and the AMX dose. Use a suitable container and dilute the calculated quantity of AMX in sea water. Diluting the product in a large volume of sea water will ensure better dispersion and thereby the efficacy of the treatment. After a short period of stirring, the diluted solution must be spread evenly throughout the treatment unit. It is recommended to use a pump with low or moderate pressure to further improve an even dispersion. Do not disperse under high pressure as this may cause atomising and/or foaming.

All fish should be oxygenated during treatment. Ensure that the oxygen level is above 7 mg/litre before the treatment is initiated and that it is kept above 7 mg/litre during the entire duration of the treatment.

At water temperature below 6°C , the product's safety margin is reduced. Extra precautionary measures should be exercised if treatments are performed at low water temperatures.

The risk of intoxication may increase in fish with severe skin lesions.

Avoid treatment if large amounts of organic material are present in the sea water or if the sea-cage is overgrown, as this may reduce the efficacy of the treatment. Overgrowth of algae on the sea-cages/nets may prevent water exchange after treatment. This may extend the exposure period and increase the risk of intoxication of the fish.

Symptoms of overdosing are equilibrium problems, behaviour disturbances, gasping for air in the water surface, alteration in pigmentation and mortalities. If any of these symptoms occur, the treatment should be terminated and unmedicated sea water let in. If the fish are treated in a raised net enclosed by a tarpaulin, the tarpaulin should be removed and the net released to normal depth immediately. If water currents are low at the time of removal of the tarpaulin the use of an artificial water-current (e.g. a boat motor propeller) is recommended in order to speed up the water exchange in the treatment unit.

Treatment should not be carried out unless some degree of water current is present. Without a current the exposure period may be extended and increase the risk of overdosing.

Lack of efficacy and reduced sensitivity to deltamethrin has been observed. Suboptimal treatment regimen and frequent treatments as well as the use of pyrethroids only for sea lice treatment, can induce reduced sensitivity in the sea lice with lack of efficacy as a possible consequence.

Dead sea lice may remain on the fish for a few days after treatment (depending on the water temperature).

AMX does not prevent reinfestation with sea lice after treatment.
It may be necessary to repeat the treatment if reinfestation with sea lice occurs, but due to the environmental properties of the product (see ”Environmental information” in the section “Special warnings”) the use of the product should be kept to a minimum. As a minimum requirement a period of at least 14 days should elapse between treatments in order to provide a protection of the environment.

10. WITHDRAWAL PERIODS

5 degree days for treated Atlantic salmon
5 degree days for treated rainbow trout

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from frost.
When the container is broached (opened) for the first time, the discard date for any product remaining in the container should be worked out, using the in-use shelf-life which is specified on this package leaflet. This discard date should be written in the space provided on the carton/label.

Dilute immediately before use, discard any unused solution.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP".

Shelf life after first opening the container: 9 months

12. SPECIAL WARNINGS

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wear protective clothing (i.e. cotton overalls and nitrile rubber or neoprene gloves (0.3mm thick)) and disposable face mask when handling the product and tarpaulins and nets of treated cages.

Wear protective clothing, gloves, eye protection and a disposable face mask when mixing and administering the product.

Do not smoke, drink or eat while handling the product.

Avoid contact with the skin, eyes, nose and mouth. If clothing becomes contaminated remove without delay and wash skin thoroughly with soap and water. Change out of protective clothing and wash hands thoroughly after using the product. Launder protective clothing before re-use.

The product is of low hazard by oral and dermal routes. Inhalation of product may cause irritation to the mucous membranes and respiratory tract. Skin exposure may cause transient sensations (tingling, numbness) which disappear after a few hours. Obtain medical advice if symptoms persist.

All equipment which has been in contact with the product should be thoroughly cleaned after completion of treatment.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Pregnancy/Lactation/Lay:
The safety of the veterinary medicinal product has not been established in Atlantic salmon and rainbow trout intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Environmental information:
Deltamethrin is toxic to aquatic and sediment living species and may cause adverse effects in the vicinity of treated sea cages. Also at distances of up to 4 kilometers downstream short term effects after treatment can be seen in sensitive organisms. Deltamethrin demonstrates high affinity to organic matter and particles in the water column and in sediments. Deltamethrin is very stable and slowly degradable when bound to sediments, both at aerobic and anaerobic conditions.

The environmental risk assessment of deltamethrin, is based on the theoretical use of only a single (annual) application in a single cage at one site. More 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 AMX 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. Please also refer to sections “Advice on correct administration” and “Special precautions for disposal”.

Other precautions:
The substance is toxic to crustaceans and should not be used in sea farms where crabs or lobsters are kept in the close vicinity of the treated sea-cages (<200 m), or when local water-currents increase the likelihood of exposure.
To prevent toxic effects on local aquatic organisms and to prevent toxic waste of deltamethrin to be washed into the littoral zone, bath treatment should be performed at outgoing tide or during periods with a local outgoing current.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

This formulated product is designed for the treatment of fish. However, at levels greater than the treatment dose, the product could be harmful to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

Vm 21714/4004

Pack sizes:
250 ml and 1000 ml

Not all pack sizes may be marketed.

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