SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SLICE 2 mg/g premix for medicated feeding stuff for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Emamectin benzoate 2.00 mg
(equivalent to 1.76 mg of Emamectin)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propylene glycol Ph. Eur.	25 mg
Butylhydroxyanisole	0.1 mg
Maize starch Ph.Eur	
Maltodextrin M100	

A white to off-white free flowing powder.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon (*Salmo salar*).

3.2 Indications for use for each target species

For the treatment and prevention at group level of infestations of all parasitic stages of sea lice (*Lepeophtheirus* sp. and *Caligus* sp.) on Atlantic salmon (*Salmo salar*) ranging in size from smolts in freshwater (just prior to transfer to seawater) to market weight fish in seawater.

3.3 Contraindications

Do not use in adult Atlantic salmon intended for broodstock.
Do not use for treatment of smolts in freshwater cages due to potential environmental risks.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Personal protective equipment, consisting of gloves, protective work clothing, dust mask and safety glasses with side shields should be worn when handling the veterinary medicinal product in the preparation of medicated fish feed.
Wash hands thoroughly with soap and water after handling the product or medicated feed and before eating or smoking.
Do not smoke or eat while handling the medicated feed.
Special precautions for the protection of the environment:

See section 5.5.

3.6 Adverse events

Atlantic salmon (*Salmo salar*):

Very common (>1 animal / 10 animals treated):	Decreased appetite[1]

[1]A change in the source and pellet size of the medicated diet may have contributed to this effect.

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 the package leaflet for contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Administer medicated feed to fish at the recommended feeding rate of 0.5% biomass/day for 7 days which will yield a dose rate of 50 micrograms/kg biomass/day.

If the feeding rate differs from 0.5% biomass/day, then the concentration of the veterinary medicinal product in feed must be adjusted proportionately. The following table is provided for reference.

Feeding rate (% biomass of fish)	Concentration of emamectin benzoate in feed medicated with the veterinary medicinal product(mg/kg)	Quantity of the veterinary medicinal product per 1,000 kg of medicated feed (kg)	Quantity of the veterinary medicinal product-medicated feed per 1,000 kg of fish per day (kg)
0.25	**20.0**	**10.0**	**2.5**
0.5	**10.0**	**5.0**	**5.0**
1.0	**5.0**	**2.5**	**10.0**
2.0	**2.5**	**1.25**	**20.0**
3.0	**1.67**	**0.833**	**30.0**
4.0	**1.25**	**0.625**	**40.0**

The fish feed medicated with the veterinary medicinal product is to be prepared only at commercial fish feed mills and not at fish farms. The veterinary medicinal product is to be coated onto feedstuff of the following type: Extruded cylindrical pellets of varying thickness and length, e.g., 3.5 mm, 5.0 mm, 7.0 mm and 10.0 mm.

Recommended Method of Incorporation:
The veterinary medicinal product may be coated onto the surface of non-medicated fish feed in the following manner:

a. Standard feed is transported by a conveyor belt to a fractioning sieve where dust and fragments are sorted out.
b. The sorted pellets are transferred to an intensive mixer.
c. The pellets are dry-mixed/coated with a pre-determined amount of the veterinary medicinal product for up to 2 minutes.
d. 0.5% to 1% fish or vegetable oil is added and mixing continued for up to 5 minutes. The added oil seals the premix powder to the feed pellet.
e. At the completion of mixing, the product is transferred to a feeder tank for packaging into sacks.

The recommended maximum number of marine treatments is 5 per 2 year growth cycle and not more than 3 per 12 month period.

Smolts should only be treated when raised either in tanks or in flowing waterways (see contra-indications).
Smolts should be transferred to seawater 1 - 2 days after the seven day treatment period has ended.

To reduce the possibility of resistance development in sea lice it is recommended that emamectin benzoate is used in integrated control programmes with the following considerations:

- Administration of the correct dosage rate over the full seven day period

- Medication of an appropriate amount of feed to ensure complete and homogeneous consumption
- Careful feeding practices to monitor feeding behaviour
- Use of the product in the absence of any intercurrent disease affecting appetite
- Simultaneous medication of all fish on a site
- Coordination of treatments of all farms in a loch or bay system to reduce cross-infestation
- Use of good management practices such as single age sites, all-in-all-out systems and fallowing between production cycles
- Use in rotation with other authorised therapeutic agents and/or in collaboration with other natural agents such as cleaner fish.

It is important that the level of infestation and the effectiveness of control measures are monitored by routine counting of sea lice stages on samples of representative fish. Counts should be conducted on at least five fish from each of 20% of cages on the farm at weekly intervals in summer and every second week in winter. Treatment should only be initiated when the number of sea lice per fish reaches a level so that effective sea lice population control can be established.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Emamectin benzoate administered to Atlantic salmon smolts in freshwater at 5.4 times the recommended dose produced dark skin colouration and incoordination during the treatment period.

Emamectin benzoate administered to Atlantic salmon in seawater at seven times the recommended dose produced lethargy, dark skin colouration and incoordination commencing on the fifth day of medication and inappetance commencing two days after treatment.

Recovery was not evident in the week following treatment, in either fish treated in freshwater or in seawater. There is no known antidote.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

3.12 Withdrawal periods

Zero days.

To ensure that tissue residues do not exceed the MRL, fish must not be treated more than once in the 60 days prior to the first fish being harvested for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA06

4.2 Pharmacodynamics

Emamectin benzoate is a semi-synthetic avermectin. Avermectins are macrocyclic compounds produced by the soil microorganism *Streptomyces avermitilis* and are characterised by a 16-membered lactone ring with an attached dioleandrosyl group.

The precise mechanism by which emamectin benzoate kills the various sea lice species has not been elucidated. However, extensive research on the mode of action of avermectin compounds against invertebrate species has shown that the avermectins competitively bind to glutamate-gated chloride channels on invertebrate nerves. The distribution of glutamate-gated chloride channels in the invertebrate may be localised to specific muscles such as those of the pharyngeal pump.

4.3 Pharmacokinetics

Emamectin benzoate is relatively slowly absorbed but it is also widely distributed to the tissues. Excretion is also relatively slow.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after incorporation into meal or pelleted feed: 6 months

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Container: Laminate Foil Pouch (12” x 15” or 13” x 16”) composed of polypropylene/low density polyethylene/aluminium foil. Fill weight 2.5 kg/pouch.

Closure: Pouch is heat sealed on three sides

Package Size: 2.5 kg pouch
Fibre Drum containing 8 x 2.5 kg pouches

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as emamectin benzoate may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 06376/3005

8. DATE OF FIRST AUTHORISATION

13 January 2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 09 December 2024