ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Pouch

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each g contains:

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

Excipients:
Propylene glycol Ph. Eur. 25 mg
Butylhydroxyanisole 0.1 mg

A white to off-white free flowing powder.

3. PACKAGE SIZE

2.5 kg
8 x 2.5 kg

4. TARGET SPECIES

Atlantic salmon (*Salmo salar*).

5. INDICATIONS FOR USE

Indications for use
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.

6. CONTRAINDICATIONS

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.

7. SPECIAL WARNINGS

Special warnings

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.

Interactions with other medicinal products and other forms of interaction:
None known.

Overdose:
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.

Special restrictions for use and special conditions for use:
This veterinary medicinal product is intended to be used for the preparation of medicated feed.

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

Special precautions for the protection of the environment:
See section special precautions for disposal.

8. ADVERSE EVENTS

Adverse events

Atlantic salmon:

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 product. If you notice any side effects, even those not already listed on this label, or

you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder<or the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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**

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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.

11. WITHDRAWAL PERIODS

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.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions
Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 06376/3005

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

Pack sizes
2.5 kg pouch
Fibre Drum containing 8 x 2.5 kg pouches

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:
Intervet GesmbH Vienna
Siemensstrasse 107
Wien 1210
Vienna, Austria

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.>
{to be completed nationally}

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after incorporation into meal or pelleted feed: 6 months

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 09 December 2024