# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

SLICE 2 mg/g premix for medicated feeding stuff.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | | |
|---|---|---|
| Each gram contains: | | |
| **Active substance:** | | |
| Emamectin benzoate | 2.00 | mg |
| (equivalent to 1.76 mg of Emamectin) | | |
| **Excipient(s):** | | |
| Propylene glycol | 25 | mg |
| Butylated Hydroxyanisole | 0.1 | mg |
| For a full list of excipients, see section 6.1. | | |

## 3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
A white to off-white free flowing powder.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Atlantic salmon (*Salmo salar*).

### 4.2 Indications for use, specifying the 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.

### 4.3 Contraindications

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

### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

**Special precautions for use in animals**
Not applicable.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**
Wear gloves, protective work clothing, dust mask and safety glasses with side shields when handling SLICE 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.

## 4.6 Adverse reactions (frequency and seriousness)

At the recommended dose emamectin benzoate produced no undesirable effects in the clinical trials, apart from a slight reduction in appetite during the medication period in two trials. A change in the source and pellet size of the medicated diet may have contributed to this effect.

## 4.7 Use during pregnancy, lactation or lay

Pregnancy:
Not applicable.

Lactation:
Not applicable.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

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 SLICE 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 SLICE (mg/kg) | Quantity of SLICE per 1,000 kg of medicated feed (kg) | Quantity of SLICE 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 |

SLICE-medicated fish feed is to be prepared only at commercial fish feed mills and not at fish farms. SLICE 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:
SLICE 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 SLICE 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.

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

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.

## 4.11 Withdrawal Period(s)

Zero days.

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

# 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Avermectin class of endectocides
ATC vet code: QP54AA06

## 5.1 Pharmacodynamic properties

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.

## 5.2 Pharmacokinetic properties

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

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Propylene glycol
Butylated hydroxyanisole
Maize starch
Maltodextrin M-100

## 6.2 Incompatibilities

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

## 6.3 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

## 6.4 Special precautions for storage

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

## 6.5 Nature and composition of immediate packaging

**Container:** Laminate Foil Pouch (12” x 15”) 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

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

# 7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

# 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/257/001

# 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st September 2010

## 10 DATE OF REVISION OF THE TEXT

January 2012