[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquaflor® vet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Florfenicol 500 mg/g

Excipients

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feed.

4. CLINICAL PARTICULARS

4.1 Target species

Salmon

4.2 Indications for use, specifying the target species

Salmon: furunculosis caused by *Aeromonas salmonicida*. Cold-water vibrosis caused by *Vibrio salmonicida*.

4.3 Contraindications

None known.

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

Avoid contact with skin and eyes when mixing the product into the fish feed. Avoid inhalation of dust from the product. It is recommended to use gloves and protective mask. Wash hands after handling of Aquaflor vet. Feeding equipment and containers must be thoroughly washed after preparation of medicated feed. Aquaflor vet. should only be used for treatment of fish.

Keep out of the sight and reach of children.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

10 mg florfenicol (20 mg premix) pr kg bodyweight added to the feed in 10 consecutive days. The mixing ratio depends on the appetite of the fish. A feeding ratio of 0.5 % means 4 kg Aquaflor vet. premix pr tons feed. This is sufficient for a one day treatment of 200 tons of fish.

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

Aquaflor vet. has been given to fish in doses 10 times higher than recommended without seeing any adverse events. No symptoms of overdoses are known.

4.11 Withdrawal period(s)

150 degree days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: florfenicol is a synthetic, broad-spectrum, bacteriostatic antibiotic with effect on most Gram-positive and Gram-negative bacteria isolated from companion animals and fish.

ATCvet code: QJ01 BA90.

5.1 Pharmacodynamic properties

Aquaflor vet. is a fine white powder containing 50 % (w/w) florfenicol with inactive ingredients of lactose monohydrate (47 %) og povidon (3 %). Florfenicol is slightly soluble in water while both lactose and povidon is soluble in water. The product should be mixed in the feed to prepare a medicated feed mix for treatment of infections caused by bacteria sensitive for florfenicol.

The bacteriostatic property of florfenicol is because of its ability to inhibit the protein synthesis due to binding of bacterial ribosomes in a way that prevents conversion of mRNA to proteins.

In vitro studies have showed florfenicols broad-spectrum activity that includes aerobe- and anaerobe-, both Gram-positive - and Gram-negative bakteria. MIC values for *Aeromonas salmonicida* is usually 0.4 – 0.8µg/ml. Florfenicol is also active towards *Vibrio anguillarum* og *Vibrio salmonicida*.

5.2 Pharmacokinetic particulars

Florfenciol has been given orally to atlantic salmon in pharmakocinetic studies. Absorption: is quickly absorbed from the intestinal tract after administration in feed. The product is well distributed in body fluid and tissue, shown with a distribution volume of 0.9 l/kg. Florfenicol has an oral bioavailability of 96.5 %.

After oral administration of a single dose florfenicol reach max. plasma concentration of 4 µg/ml 10.3 hours after administration of 10 mg/kg bodyweight. Half-life at 12 °C is 12.2 hours, after one single dose. Excretion is usually via urine and bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidon

6.2 Incompatibilities

None known.

6.3 Shelf life

Aquaflor vet. has a shelf life of 3 years, when stored at 2 – 30 °C.

6.4. Special precautions for storage

Store at 2 – 30 °C. Keep away from other feed and feed additives.

6.5 Nature and composition of immediate packaging

Aquaflor vet. is packed in aluminium lined bags of 2 kg. 8 laminated bags of 2 kg are packed in a 16 kg fiber barrel.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

7969

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07.04.1994.
Date of last renewal: 06.05.2004.

10 DATE OF REVISION OF THE TEXT

2009-10-09