ANNEX III

LABELLING AND PACKAGE LEAFLET

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquaflor 500 mg/g premix for medicated feeding stuff for trouts

Aquaflor 500 mg premix for medicated feeding stuff

2. COMPOSITION

Each g contains:

Active substance:
Florfenicol 500 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Povidone K29/32

A white free flowing powder.

3. PACKAGE SIZE

2 kg

4. TARGET SPECIES

5. INDICATIONS FOR USE

Indications for use
For the treatment and metaphylaxis of furunculosis in rainbow trout caused by *Aeromonas salmonicida* susceptible to florfenicol in freshwater fisheries. The presence of the disease should be established in the holding unit before initiating the treatment.

6. CONTRAINDICATIONS

Contraindications
Do not use in broodstock.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer together with other antimicrobial products.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
In order to maximize feed uptake throughout the population to be treated, medicated feed should be administered following the same feeding regimen as was used prior to treatment, to the greatest degree possible.
To minimize stress and ensure that all medicated feed is consumed in the infected shoal, daily feed may be reduced compared to the usual feeding rates.
Care should be taken when administering medicated feed by hand that feed pellets are widely dispersed to minimize hierarchical feeding behaviour.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol. The veterinary medicinal product should only be used in freshwater fisheries for the treatment of furunculosis in trout. A full benefit-risk analysis has not been performed for use in marine aquaculture, especially with regards to the environmental risk. The use of the veterinary medicinal product should always be combined with good management practices of the freshwater fisheries (e.g. vaccination programmes, biosecurity, water quality and site hygiene).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity reactions (allergy) People with known hypersensitivity to florfenicol should avoid contact with the veterinary medicinal product.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable half-mask respirator to European Standard EN 140 with a filter to EN 143
Avoid contact with the skin and eyes. Wear chemically resistant gloves, protective overalls and safety glasses while incorporating the premix into the feed.
Wear gloves and do not smoke, drink or eat while handling the product or medicated feed. Wash hands thoroughly with soap and water after use of the product or medicated feed. Clean thoroughly all equipment used for medicating feed.
In case of accidental self-ingestion seek medical advice immediately and show the package leaf-let or the label to the physician.

Overdose:
No adverse reactions were observed after treatment of rainbow trout with 5 times the recommended dose of florfenicol.

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.

8. ADVERSE EVENTS

Adverse events

None known.

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

In-feed use. For the preparation of medicated feeding stuff.

The premix should be mixed into or on feed to deliver a total daily dose rate of 10 mg of florfenicol per kg body weight during 10 consecutive days.

The entire daily ration of medicated feed should be administered first for each day of the 10-day dosing period. If the feeding rate exceeds 0.4% of the biomass, non-medicated feed may be administered after the medicated ration, or a lower incorporation rate may be chosen for the preparation of medicated feed. If the feeding rate is ≤ 0.4% of the biomass, then the daily ration should consist of only medicated feed and be administered at one time.

Administration of medicated feed should begin immediately following diagnosis to ensure that fish are able to consume the complete medicated ration.

This veterinary medicinal product should be incorporated by licensed feed manufacturers only. An incorporation rate of 0.5% or 5 kg premix/ton feed is recommended; however, lower mixing rates can be used when higher feeding rates need to be covered. The concentration of medicated premix in feed should be ≥ 0.04% or 0.4 kg premix/ton feed.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Mixing Instructions:

During the preparation of medicated feed, the premix is either coated onto the surface of the pellet or incorporated into the feed ingredient mash prior to extrusion or pelleting.

Top-coating:

Method 1: The dry premix is thoroughly mixed with feed which typically contains 24 – 38% w/w lipid. Approximately 0.5 % w/w oil is then added to the premix/feed mixture to improve both premix adhesion and palatability.

a) Add known quantity of fish feed into a mixer.
b) Weigh the premix.
c) Mix premix with feed pellets.
d) Medicated feed pellets are mixed/coated with a predetermined amount of fish or vegetable oil.
e) At the completion of mixing, the veterinary medicinal product is transferred to a storage tank for packaging or transport.

Method 2: The dry premix is mixed with oil. The premix/oil preparation is then added to the feed to produce palatable medicated feed pellets.

a) Weigh out fish or vegetable oil into a bucket.
b) Weight out the premix and mix thoroughly with oil in the bucket
c) Add a known quantity of fish feed into a mixer.
d) Add the premix and oil mixture to the feed in the mixer, slowly, while the mixer is running at low speed. At the completion of mixing, the veterinary medicinal product is transferred to a storage tank for packaging or transport.

Extrusion or Pelleting:

The dry premix is added directly to the feed ingredient mash and mixed thoroughly. Water and steam are added, and the complete mixture is then extruded or pelleted, dried and packed.

a) The premix is added directly to the feed ingredient mash and mixed thoroughly to ensure homogeneity.
b) The mixture is steam pelleted and or extruded and the pellets are dried.
c) Medicated feed pellets are mixed/coated with a pre-determined amount of fish or vegetable oil.
d) At the completion of mixing, the veterinary medicinal product is transferred to a storage tank for packaging or transport.

Recommended premix inclusion rate for preparation of medicated feed

Feeding Rate	**Amount of premix per metric ton of feed**	**Amount of florfenicol per feed in mg/kg**	**Kilograms of fish medicated per metric ton of feed for 10-d treatment period**
% biomass	**kg**	**mg**	**kg**
0.2	10	5000	50,000
0.3	6.7	3333	33,333
0.4	5	2500	25,000
0.5	4	2000	20,000
1.0	2	1000	10,000
2.0	1	500	5,000
3.0	0.66	330	3,300
5.0	0.40	200	2,000

The formula for calculation of the amount of premix to be added to feed to produce medicated feed at ≥ 0.4 kg premix/ton feed is as follows:

$$\frac{\text{20 mg premix (= 10 mg florfenicol) per kg body weight and day} \times \text{Average fish weight (kg)}}{\text{Average daily feed intake (kg/fish)}} = \text{mg premix per kg of feed}$$

11. WITHDRAWAL PERIODS

Withdrawal periods
135 degree days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Premix: The veterinary medicinal product does not require any special temperature storage conditions.
Store in a dry place.
Keep separate from feeds and foodstuffs.
Medicated feed: Do not store at temperatures above 25°C.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.
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

XXXXX

Pack sizes

Bag of 2 kg.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised
{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Manufacturer responsible for batch release:

Intervet GesmbH
Siemensstrasse 107
A-1210 Vienna
Austria

<Local representatives <and contact details to report suspected adverse reactions>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.>

18. OTHER INFORMATION

<Other information>

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life of the veterinary medicinal product as packed for sale: 3 years
Shelf life after first opening the immediate packaging: 3 months
Shelf life after incorporation into meal or pelleted feed: 3 months

Once opened, use by…

21. BATCH NUMBER

Lot {number}