

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Florocol 500 mg/g premix for medicated feeding stuff for rainbow trouts

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer for the batch release:

Intervet GesmbH
Siemensstrasse 107
A-1210 Vienna
Austria

MSD Animal Health UK Ltd.
Walton Manor, Walton, Milton Keynes
Buckinghamshire
MK7 7AJ
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Florocol 500 mg/g premix for medicated feeding stuff for rainbow trouts
Denmark: Florocol Vet. 500mg/g premix for medicated feeding stuff for rainbow trouts

Florfenicol

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1g premix contains 500 mg florfenicol.
A white free flowing powder.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in broodstock.
Do not use in animals with known hypersensitivity to the active ingredient.
Do not administer together with other antimicrobial products.

6. ADVERSE REACTIONS

None. If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Rainbow trout (*Oncorhynchus mykiss*)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 $\leq 0.4\%$ 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 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 $\geq 0.04\%$ or 0.4 kg premix/ton feed.

9. 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 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) Weigh 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 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 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:

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

10. WITHDRAWAL PERIOD

135 degree days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Premix: The medicinal product does not require any special storage conditions.

Store in a dry place.

Keep separate from feeds and foodstuffs.

Do not use this veterinary medicinal product after the expiry date which is stated on this label after EXP.

Shelf life after first opening the container: 3 months

Shelf life after incorporation into meal or pelleted feed: 3 months

Medicated feed: Do not store at temperatures above 25 °C.

12. SPECIAL WARNINGS

Special warnings for each target species

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 use in animals

Use of the 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 product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to florfenicol. The 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 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

In case of accidental self-ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to the active ingredient should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with a filter to EN 143, chemically resistant gloves, protective coveralls, and safety glasses should be worn when handling the veterinary medicinal product.

Do not eat, drink or smoke while handling the product or medicated feed. Wash hands thoroughly with soap and water after use of the product or medicated feed. Thoroughly clean all equipment used in medicating feed.

Overdose (symptoms, emergency procedures, antidotes)

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

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<To be completed nationally>

15. OTHER INFORMATION

2 kg laminated sachet consisting of polypropylene/ low density polyethylene/ aluminium foil/ Surlyn ionomer heat sealant.

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

16. EXPIRY DATE

EXP:

Once opened, use by

17. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only - to be supplied only on veterinary prescription.

18. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

19. MANUFACTURER’S BATCH NUMBER

Batch No.

20. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>