SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Florocol Premix for Medicated Feeding stuff 500mg/g for Atlantic Salmon

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 feeding stuff.

A white free flowing powder.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon.

4.2 Indications for use, specifying the target species

For the treatment of furunculosis (*Aeromonas salmonicida*) infection of Atlantic salmon.

4.3 Contraindications

Do not use in brood stock.

4.4 Special warnings for target species

None**.**

4.5 Special precautions for use

Special precautions for use in animals:
Use of the product should be based on susceptibility testing of the strain of bacteria isolated from the fish. If this is not possible, therapy should be based on local

(regional, farm level) epidemiological information about susceptibility of the target bacteria.
Chloramphenicol type antibacterials may prolong the effects of anaesthetics.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wear either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143, chemically resistant gloves, protective coveralls and goggles while incorporating the premix into the feed.
Wear gloves and do not smoke or eat 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.

Other precautions:
In the UK, it is essential to obtain a discharge consent from the local regional office of the Environment Agency or SEPA.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation and lay

Not applicable.

4.8 Interactions with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

In-feed use.

Dose: 10 mg/kg bodyweight. The incorporation rate in feed must be calculated to achieve this dosage. Affected fish should receive the medicated feed daily for 10 consecutive days.

The intake of medicated feed depends on the clinical condition of the fish. In order to ensure the correct dosage is administered, the concentration of Florocol in feed must be adjusted accordingly.

For incorporation into dry feed at a registered mill.
A manufacturer who is approved to incorporate veterinary medicinal products or premixtures containing such products directly at any concentration must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

The premix should be mixed with oil before incorporation in to dry feed.

To ensure thorough dispersion, the product should first be mixed with, or surface-coated onto, a suitable quantity of feed before incorporation in the final mix.

Table: Examples of incorporation rates:

Feeding rate (as % of fish bodyweight)	Quantity (kg) of Florocol per tonne of medicated feed	Fish (kg) medicated daily per tonne of medicated feed
0.5	4	200,000 kg
1.0	2	100,000 kg
2.0	1	50,000 kg

4.10 Overdose

No adverse effects were seen at up to ten times the recommended dose.

4.11 Withdrawal period(s)

150 degree days.
(15 days from the last treatment at 10 °C)

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; amphenicols; florfenicol
ATCvet code: QJ01BA90

5.1 Pharmacodynamic properties

Florfenicol is a broad-spectrum antibiotic which is active against both Gram-positive and Gram-negative bacteria isolated from domestic animals.

Florfenicol is a bacteriostatic antibiotic. Its activity is due to inhibition of protein synthesis and results from the binding of bacterial ribosomes in such a way as to prevent ongoing translation of mRNA into protein. *In vitro* studies have shown florfenicol to have a broad spectrum of activity which includes aerobic and anaerobic bacteria which are either Gram-positive or Gram-negative.
Aeromonas salmonicida has been shown to be sensitive to florfenicol concentrations of 1.6 µg/ml or less.

5.2 Pharmacokinetic particulars

Pharmacokinetic studies have been conducted with florfenicol following oral administration to Atlantic salmon. After oral administration florfenicol reached a peak plasma concentration of 4 µg/ml at 10.3 hours after administration. The drug was well distributed in body fluids and tissues as demonstrated by a volume of distribution of 0.9 L/kg. Florfenicol had an oral bioavailability of 96.5%.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after incorporation into pelleted feed: 3 months.

6.4 Special precautions for storage

Do not store above 30°C.
Protect from light.
Store in a dry place.
Store away from food, drink and animal feeding stuff.

6.5 Nature and composition of immediate packaging

Laminated sachet consisting of polypropylene/low density polyethylene/aluminium foil.

Package size: 2 kg.

6.6 Special precautions for the disposal of unused product or waste materials

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4130

9. DATE OF FIRST AUTHORISATION

13 September 1999

10. DATE OF REVISION OF THE TEXT

August 2025

Gavin Hall
Approved: 12 August 2025