**AQUAFLOR TYPE A MEDICATED ARTICLE- florfenicol powder**
**Merck Sharp & Dohme Corp.**

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**Aquaflor®**
**(Florfenicol)**

**Type A Medicated Article**
**For Use in Freshwater-reared Finfish Feeds Only**

**Do Not Feed Undiluted**

## CAUTION

Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

## Active Drug Ingredient

Florfenicol 500 g per kg (227.27 g per lb)

## Inert ingredients

Lactose and Povidone.

## Description

Each kg of Aquaflor® (florfenicol) contains 500 g (1.1 lb) of florfenicol in a palatable base.

## Indications

| Fish Species | Indication | Florfenicol (mg/kg body weight/day) | Florfenicol (grams/ton) |
|---|---|---|---|
| Freshwater-reared salmonids | For the control of mortality due to furunculosis associated with *Aeromonas salmonicida*. | 10 - 15 | 182-2,724 |
| | For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum*. | | |
| Freshwater-reared finfish | For the control of mortality due to columnaris disease associated with *Flavobacterium columnare*. | 10 - 15 | 182-2,724 |
| Catfish | For the control of mortality due to enteric septicemia of catfish | 10 - 15 | 182-2,724 |

| | | | |
|---|---|---|---|
| Catfish | associated with *Edwardsiella ictaluri*. | 10 - 15 | 182-2,724 |
| Freshwater-reared warmwater finfish | For the control of mortality due to streptococcal septicemia associated with *Streptococcus iniae*. | 15 | 273- 2,724 |

**Caution:** Not for use in animals intended for breeding purposes. The effects of florfenicol on reproductive performance have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy. For catfish, a dose related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for the hematopoietic/lymphopoietic tissues to regenerate was not evaluated.

## RESIDUE WARNING

Feeds containing Aquaflor® (florfenicol) must be withdrawn 15 days prior to slaughter.

## IMPORTANT

This product has been evaluated in salmonid and catfish feeds and should be used in feeds nutritionally similar to these evaluated feeds. Refer to the Freedom of Information Summary for details. Must be thoroughly mixed in feeds or surface-coated (top-coated) onto the feeds before use.

### Mixing Instructions

**For incorporation into feed pellets:** For making Aquaflor® (florfenicol) Type C Medicated Feed:

a) Aquaflor® (florfenicol) is added to other feed ingredients in the mixer prior to extrusion,
b) the ingredients are mixed thoroughly to insure homogeneity,
c) the mixture is steam pelleted or extruded and pellets are dried,
d) medicated feed pellets are mixed/coated with a predetermined amount of fish or vegetable oil, and
e) at the completion of mixing, the product is transferred to a storage tank for packaging or transport.

**For surface-coating (top-coating) onto feed pellets:** There are two methods for making Aquaflor® (florfenicol) Type C Medicated Feed by top-coating.

### Method 1:

a) add a known quantity of fish feed into a mixer,
b) weigh out Aquaflor® (florfenicol),
c) mix Aquaflor® with feed pellets,
d) medicated feed pellets are mixed/coated with a predetermined amount of fish or vegetable oil, and
e) at the completion of mixing, the product is transferred to a storage tank for packaging or transport.

**Method 2:**

a) weigh out fish oil or vegetable oil into a bucket,
b) weigh out Aquaflor® (florfenicol) and mix thoroughly with the oil in the bucket,
c) add a known quantity of fish feed into a mixer,
d) add the Aquaflor® (florfenicol) and oil mixture to the feed in the mixer, slowly, while the mixer is running at low speed,
e) at the completion of mixing, the product is transferred to a storage tank for packaging or transport.

**Example of Aquaflor® (florfenicol) Inclusion Rates for Preparation of Type C Medicated Feed**

| Feeding Rate | Florfenicol Concentration in Feed | | Amount of Aquaflor® (florfenicol) per Ton of Feed | | Biomass of Fish Medicated per Ton of Feed per 10-day Treatment Period |
|---|---|---|---|---|---|
| % Biomass | Grams/ton | | lbs | | lbs |
| | Dose 10 mg/kg | Dose 15 mg/kg | Dose 10 mg/kg | Dose 15 mg/kg | |
| 0.5 | 1,816 | 2,724 | 8 | 12 | 40,000 |
| 1 | 908 | 1,362 | 4 | 6 | 20,000 |
| 2 | 454 | 681 | 2 | 3 | 10,000 |
| 3 | 300 | 450 | 1.32 | 1.98 | 6,666 |
| 5 | 182 | 273 | 0.8 | 1.2 | 4,000 |

**Feeding Directions**

Feed as the sole ration for 10 consecutive days. Aquaflor® (florfenicol) medicated feed should only be administered once disease has been appropriately diagnosed. Feeding fish at a percent of biomass and corresponding florfenicol concentration included in the table above will deliver the appropriate florfenicol dose.

**Caution**

Feed containing Aquaflor® (florfenicol) shall not be fed to finfish for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating a further course of therapy. The expiration date for VFD for Aquaflor® (florfenicol) must not exceed 6 months from the date of issuance. VFD for Aquaflor® (florfenicol) shall not be refilled.

Sunburn, skin lesions, and skin sloughing have been reported in salmonids treated with florfenicol. Not all adverse drug events are reported to FDA CVM. It is not always possible to reliably estimate the adverse event incidence or to establish a causal relationship to product exposure using this data alone.

Before using this drug for the first time, you must inform the appropriate National Pollutant Discharge Elimination System (NPDES) permitting authority of your intentions and of the following information. Acute and chronic water quality benchmarks for the protection of freshwater aquatic life have been derived by FDA for florfenicol following

EPA guidance for calculating Tier II water quality criteria for the Great Lakes System (40 CFR 132, App. A). The acute benchmark value (Secondary Maximum Concentration) is 20.6 mg/L (equivalent to one-half of the Secondary Acute Value). The chronic benchmark value (Secondary Continuous Concentration) is 0.23 mg/L (equivalent to the Final Plant Value). The NPDES authority may require an NPDES permit before you can discharge Aquaflor®. The water quality benchmark concentrations are not discharge limits, but may be used by the NPDES authority to derive such limits for the permit. Additional environmental information on Aquaflor® and the benchmark values are available in an environmental assessment posted at https://animaldrugsatfda.fda.gov/adafda/views/#/environmentalAssessments

## WARNING

Avoid inhalation, oral exposure, and direct contact with skin or eyes. Operators mixing and handling Aquaflor® (florfenicol) should use protective clothing, gloves, goggles and NIOSH-approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention. Not for human consumption. Keep out of reach of children. The Safety Data Sheet (SDS) contains more detailed occupational safety information. For more information or to report adverse effects, call 1-800-224-5318. For customer service, call 1-800-521-5767. For a copy of SDS sheet, call 1-800-770-8878.

## STORAGE CONDITIONS

Store at temperatures up to 25°C with excursions permitted to 40°C.

Approved by FDA under NADA # 141-246

Formulated in Austria.
Rev. 6/2022

LOT:
EXP:

MERCK
Animal Health


354296 R4

## PRINCIPAL DISPLAY PANEL - 2 kg Pouch Label

2 kg (4.4 lb)

Aquaflor®

(Florfenicol)
Type A Medicated Article
For Use in Freshwater-reared Finfish Feeds Only

Do Not Feed Undiluted

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Active Drug Ingredient: Florfenicol 500 g per kg (227.27 g per lb)

Description: Each kg of Aquaflor® (florfenicol) contains 500 g (1.1 lb) of florfenicol in a palatable base.

Approved by FDA under NADA # 141-246


Florfenicol (active ingred.) made in China. Formulated in Austria.

Rev. 6/2022

MERCK
Animal Health

368029 R4


**AQUAFLOR TYPE A MEDICATED ARTICLE**
florfenicol powder

| Product Information | | | |
|---|---|---|---|
| **Product Type** | VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG | **Item Code (Source)** | NDC:0061-1355 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **FLORFENICOL** (UNII: 9J97307Y1H) (FLORFENICOL - UNII:9J97307Y1H) | FLORFENICOL | 500 g in 1 kg |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0061-1355-01 | 2 kg in 1 POUCH | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NADA | NADA141246 | 03/28/2012 | |

## Labeler - Merck Sharp & Dohme Corp. (001317601)

Revised: 9/2025 Merck Sharp & Dohme Corp.