AQUAFLOR®

(florfenicol) TYPE A MEDICATED ARTICLE

PRODUCT BULLETIN

Approved for use in all freshwater-reared finfish with more indications.

DEPENDABLE

- **Controls columnaris** in all finfish and other major bacterial diseases*
- Proprietary formulation **developed specifically for aquaculture**
- Keeps fish healthy, so they stay on feed[1]
- Reduces mortality so you can produce **more fish**.

CONVENIENT

- Approved for **all freshwater-reared finfish** at dose rates of up to 15 mg/kg*
- Can be fed from **fingerlings to food fish**
- May be used in **sinking or floating feeds**
- **Stable** under high-temperature extrusion processes
- **Single withdrawal time** (15 days) for all species and indications
- **Up to 6-month** Veterinary Feed Directive (VFD) expiration

SAFE

- **No adverse effects** on fish behavior or performance, even when tested at 5X and 10X dose rates*
- **Developed specifically for fish** and food-animal species – not used in human medicine
- **Friendly to environment** – no significant risk to aquatic ecosystems
- Approved for use in **recirculating aquaculture systems**

PALATABLE

- Studies show that **fish readily consume feed with AQUAFLOR** – palatability comparable to unmedicated feed[2]
- **Minimize wasted feed**, maximize antibiotic uptake
- Uniform granulation for optimum distribution in feed and **more accurate dosage** delivery

LEARN MORE about AQUAFLOR at aquaflor-usa.com or call **800.521.5767.**

[1] Reference: Gaunt PS, Endris RG, et al. Determination of Dose Rate of Florfenicol in Feed for Control of Mortality in Channel Catfish *Ictalurus punctatus* (Rafmesque) Infected with *Edwardsiella ictaluri,* Etiological Agent of Enteric Septicemia. J World Aquac Soc. 2004;35(2): 257-267.

[2] Gaunt P, Endris RG, Khoo L, McGinnis A, Santucci T, Leard T, Jack S, Katz T, Radecki SV, Simmons R. Preliminary Assessment of the Tolerance and Efficacy of Florfenicol Against *Edwardsiella ictaluri* Administered in Feed to Channel Catfish. J Aquat Anim Health. 2003;15:239-247.

*See product label on next page for more details.

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

US-AQP-210200001

MERCK Animal Health

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*** For the control of mortality due to coldwater disease associated with ***Flavobacterium psychrophilum***	10-15	182-2,724
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 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 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 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):

There are two methods for making AQUAFLOR Type C Medicated Feed by top-coating.

Method 1:

a. add a known quantity of fish feed into a mixer,
b. weigh out AQUAFLOR,
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 and mix thoroughly with the oil in the bucket,
c. add a known quantity of fish feed into a mixer,
d. add the AQUAFLOR 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.

Do Not Feed Undiluted

2 kg (4.4 lb)

For Use in Freshwater-reared Finfish Feeds Only

Example of AQUAFLOR Inclusion Rates for Preparation of Type C Medicated Feed:

FEEDING RATE	FLORFENICOL		AMOUNT OF AQUAFLOR PER TON OF FEED		BIOMASS OF FISH MEDICATED PER TON OF FEED PER 10-DAY TREATMENT PERIOD
% of Biomass	Grams/ton		lbs		lbs
	Dose 10mg/kg	Dose 15mg/kg	Dose [1] 10mg/kg	Dose 15mg/kg	
0.5	**1,816**	**2,724**	**8.00**	**12.00**	**40,000**
1.0	**908**	**1,362**	**4.00**	**6.00**	**20,000**
2.0	**454**	**681**	**2.00**	**3.00**	**10,000**
3.0	**300**	**450**	**1.32**	**1.98**	**6,666**
5.0	**182**	**273**	**0.80**	**1.20**	**4,000**

Feeding Directions: Feed as the sole ration for 10 consecutive days. AQUAFLOR 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 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 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 the 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 found under Aquaflor®-NADA 141-246, EA for each indication posted at https://www.fda.gov/animal-veterinary/aquaculture/approved-aquaculture-drugs.

WARNING: Avoid inhalation, oral exposure and direct contact with skin or eyes. Operators mixing and handling AQUAFLOR 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.

NADA #141-246, Approved by FDA.

MERCK Animal Health