Aquaflor® (Florfenicol) Veterinary Feed Directive

14651

Client: _____ **Veterinarian:** _____

Home or Business Address _____ **Address:** _____

_____ _____

_____ _____

Phone: _____ **Phone:** _____

Approximate Number of Animals:

Animal Location:

Indications: Circle the row with the treated species and indication, and initial the corresponding box.

Fish Species	Indication	Florfenicol (mg/kg body weight/day)	Florfenicol (grams/ton)	Initials
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.*			
Catfish	For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri.*			
Freshwater-reared warmwater finfish	For the control of mortality due to streptococcal septicemia associated with *Streptococcus iniae.*	15	273 - 2,724	

Mix into Type C Medicated Feed to Provide: _____ grams florfenicol/ton (See table below.)

Feeding Rate: _____ % Biomass

Feeding Duration: Feed as the sole ration for 10 consecutive days.

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	8.00	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

Special Instructions:

Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.

This VFD only authorizes the use of the VFD drug cited in this order and is not intended to authorize the use of such drug in combination with any other animal drugs.

Caution: Feed containing Aquaflor® (florfenicol) shall not be fed to fish for more than 10 days. Following 10 days administration, fish should be reevaluated by a licensed veterinarian before starting another course of therapy. The expiration date for VFD Aquaflor® (florfenicol) must not exceed 6 months from the date of issuance. VFD for Aquaflor® (florfenicol) shall not be refilled.

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.

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

RESIDUE WARNING: Feeds containing Aquaflor® (florfenicol) must be withdrawn 15 days prior to slaughter.

Expiration Date: _____ Month/Day/Year (Not to exceed 6 months from date of issuance.)

Veterinarian's Signature: _____ **Date of issuance:** _____ (Month/Day/Year)

☐ DRUG PRODUCT SUBSTITUTION IS NOT ALLOWED.

MERCK Animal Health

Approved by FDA under NADA # 141-246

086478 Rev. 08/21

TAKE TIME
OBSERVE LABEL DIRECTIONS

White Copy - Veterinarian Canary Copy - Client Pink Copy - Feed Mill