

**Florfenicol Freshwater-Reared Finfish Feed
(florfenicol Type C Medicated Feed)**

FOR USE IN FRESHWATER-REARED FINFISH ONLY

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

Indication

For the control of mortality due to columnaris disease
associated with *Flavobacterium columnare*.

Active Drug Ingredient

Florfenicol***182 to 2,724 grams per ton*

Guaranteed Analysis

Crude Protein (min).....	%
Crude Fat (min).....	%
Crude Fiber (max).....	%
Phosphorus (min).....	%

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials (AAFCO).

Feeding Directions

Feed as a sole ration at a rate of _____% biomass daily for 10 consecutive days. Feeding at this rate will deliver 10 - 15 mg florfenicol per kg of fish**.

Caution

Feed containing PAQFLOR™ (florfenicol) shall not be fed to freshwater-reared finfish for more than 10 days. Following 10 days administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The expiration date for VFD for PAQFLOR™ (florfenicol) must not exceed 6 months from the date of issuance. VFD for PAQFLOR™ (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 hematopoietic/lymphopoietic tissue 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 PAQFLOR™. 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 PAQFLOR™ and the benchmark values are available in an environmental assessment posted at <https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadEA/113>



WARNING: Feeds containing PAQFLOR™ (florfenicol) must be withdrawn 15 days prior to slaughter.



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

Manufactured by
Blue Bird Feed Mill
Robin, IN 00000

____ lbs(kg) NET WEIGHT
BAG OR BULK
Lot number: _____

Approved by FDA under ANADA # XXX-XXX

Made in USA.

*Final printed label must bear a single drug concentration.
**Feed according to the veterinarian instructions on the VFD.
***Sourced from PAQFLOR™, ANADA # XXX-XXX

