

PAQFLOR- florfenicol powder
Phibro Animal Health

PAQFLOR™
(Florfenicol)
Type A Medicated Article

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

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

Approved by FDA under ANADA # 200-803

PAQFLOR is a trademark of Phibro Animal Health Corporation.

Phibro Animal Health Corporation, Teaneck, NJ 07666.

Lot number:

Expiration:

Net Weight: 2 kg

101-8404-01A

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.

For Use in Freshwater-reared Finfish Feeds Only

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

Inert ingredients: Lactose and Povidone.

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

Indications:

| Fish Species | Indication | Florefenicol (mg/kg body weight/day) | Florefenicol (grams/ton) |
|---------------------|----------------------------------|---|-------------------------------------|
| Freshwater-reared | For the control of mortality due | | |

| | | | |
|-------------------------------------|---|-------|-----------|
| Freshwater-reared salmonids | to furunculosis associated with <i>Aeromonas salmonicida</i> . For the control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> . | 10-15 | 182-2,724 |
| Freshwater-reared finfish | For the control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> . | 10-15 | 182-2,724 |
| Catfish | For the control of mortality due to enteric septicemia of catfish associated with <i>Edwardsiella ictaluri</i> . | 10-15 | 182-2,724 |
| Freshwater-reared warmwater finfish | For the control of mortality due to streptococcal septicemia associated with <i>Streptococcus iniae</i> . | 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 PAQFLOR™ (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 PAQFLOR™ (florfenicol) Type C Medicated

Feed: a) PAQFLOR™ (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

PAQFLOR™ (florfenicol) Type C Medicated Feed by top-coating. **Method 1:**a) add a known

quantity of fish feed into a mixer, **b)** weigh out PAQFLOR™ (florfenicol), **c)** mix PAQFLOR™

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 PAQFLOR™ (florfenicol) and mix thoroughly with the oil in the bucket,

c) add a known quantity of fish feed into a mixer, **d)** add the PAQFLOR™ (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 PAQFLOR™ (florfenicol) Inclusion Rates for Preparation of Type C Medicated Feed

| Feeding Rate | Florfenicol Concentration in Feed | | Amount of PAQFLOR™ (florfenicol per Ton of Feed) | | Biomass of Fish Medicated per Ton of Feed per 10-day Treatment Period |
|--------------|-----------------------------------|---------------|--|---------------|---|
| | | | | | |
| | Grams/ton | | lbs | | |
| % Biomass | Dose 10 mg/kg | Dose 15 mg/kg | Dose 10 mg/kg | Dose 15 mg/kg | lbs |
| 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. PAQFLOR™ (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 PAQFLOR™ (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 PAQFLOR™ (florfenicol) must not exceed 6 months from the date of issuance. VFD for PAQFLOR™ (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 PAQFLORTM. 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 PAQFLORTM and the benchmark values are available in an environmental assessment posted at <https://animaldrugsfda.fda.gov/adafda/app/search/public/document/downloadEA/113>

WARNING: Avoid inhalation, oral exposure, and direct contact with skin or eyes.

Operators

mixing and handling PAQFLOR™ (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.

CONTACT INFORMATION: To report suspected adverse drug events, for technical assistance or

to obtain a copy of the Safety Data Sheet (SDS), contact Phibro Animal Health Corporation at

888-403-0074 or www.PAHC.com. For additional information about adverse drug experience reporting

for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

Approved by FDA under ANADA # 200-803

PAQFLOR is a trademark of Phibro Animal Health Corporation.

Phibro Animal Health Corporation, Teaneck, NJ 07666.

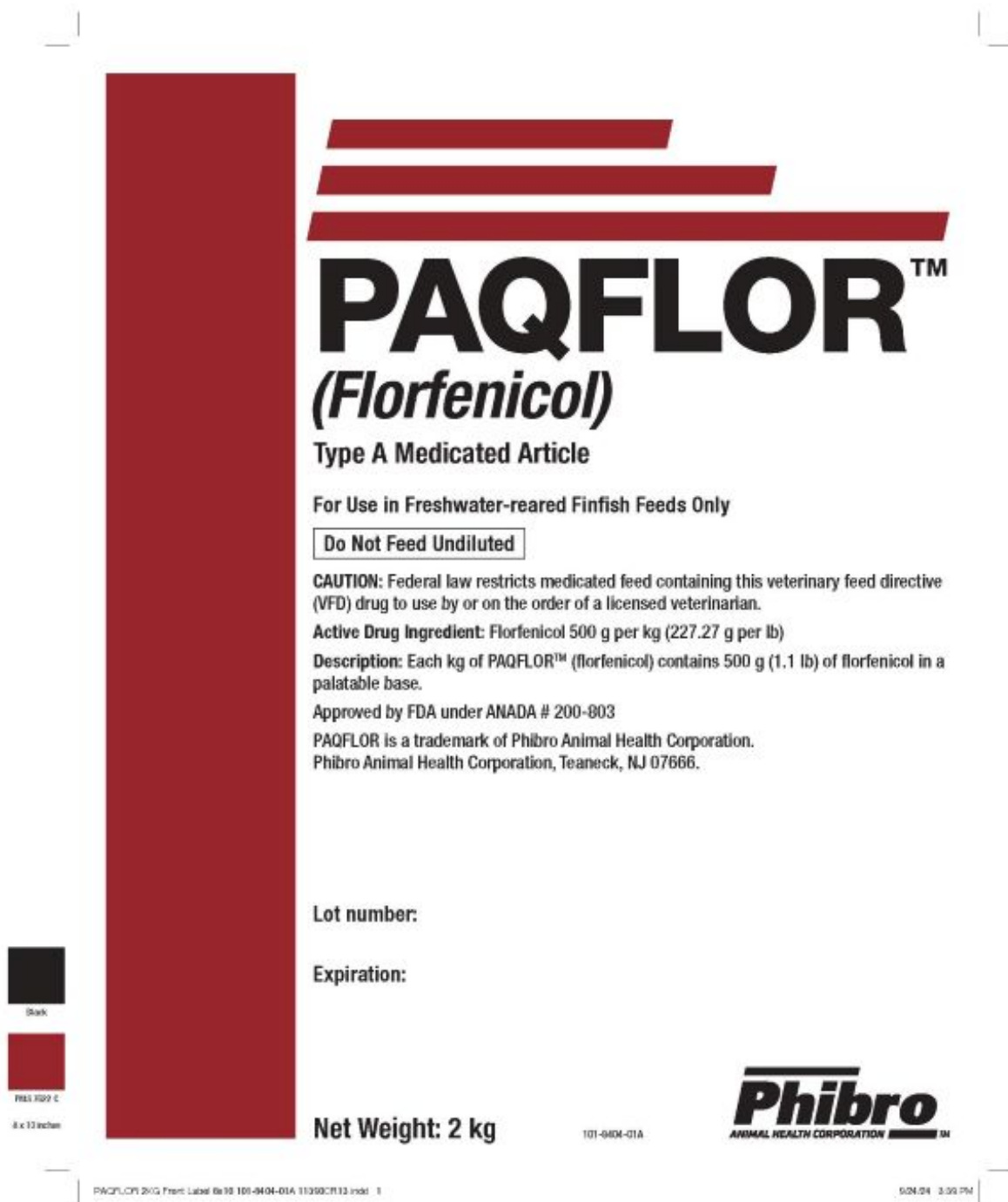
Net Weight: 2kg

101-8404-01B

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

Label

PAQFLOR Front and Back Label



PAQFLOR™

(Florfenicol)

Type A Medicated Article

For Use in Freshwater-raised Farmed Fish Only

Active Drug Ingredient: Florfenicol 500 g per kg (201.22 g per kg)

Net Weight Indicated on Label and Package

Description: Each kg of PAQFLOR™ (florfenicol) contains 500 g (1.1 lb) of florfenicol in a palatable form.

Indications:

| Fish Species | Indication | Florfenicol (mg/kg body weight/100g) | Fluorfenicol (grams/lb) |
|-------------------------------------|--|--------------------------------------|-------------------------|
| Freshwater-raised white sturgeon | For the control of morbidity due to furunculosis associated with <i>Aeromonas salmonicida</i> . | 10 - 15 | 182 - 2,724 |
| Freshwater-raised white sturgeon | For the control of morbidity due to columnar disease associated with <i>Aeromonas hydrophila</i> . | 10 - 15 | 182 - 2,724 |
| Freshwater-raised white sturgeon | For the control of morbidity due to columnar disease associated with <i>Pseudomonas columnaris</i> . | 10 - 15 | 182 - 2,724 |
| Catfish | For the control of morbidity due to columnar disease associated with <i>Aeromonas hydrophila</i> . | 10 - 15 | 182 - 2,724 |
| Freshwater-raised warmwater catfish | For the control of morbidity due to columnar disease associated with <i>Aeromonas hydrophila</i> . | 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. Florfenicol is a drug, not a feed, and may have associated the use of the florfenicol medicated feed. Florfenicol is a drug, not a feed, and may have associated the use of the florfenicol medicated feed. Florfenicol is a drug, not a feed, and may have associated the use of the florfenicol medicated feed.

RESIDUE WARNING: Florfenicol (PAQFLOR™) should be withdrawn 15 days prior to slaughter.

IMPORTANT: This product has been evaluated in rainbow trout and white sturgeon. It should be used in fish that are similar to those evaluated. Do not use in fish that are not similar to those evaluated. Do not use in fish that are not similar to those evaluated.

Mixing Instructions:

For incorporation into feed pellets: For making PAQFLOR™ (florfenicol) Type A Medicated Feed, add PAQFLOR™ (florfenicol) to the feed ingredients in the mixer until the mixture is thoroughly mixed. For making PAQFLOR™ (florfenicol) Type A Medicated Feed, add PAQFLOR™ (florfenicol) to the feed ingredients in the mixer until the mixture is thoroughly mixed. For making PAQFLOR™ (florfenicol) Type A Medicated Feed, add PAQFLOR™ (florfenicol) to the feed ingredients in the mixer until the mixture is thoroughly mixed.

Approved by FDA under ANDA 2-230-003

PAQFLOR is a trademark of Phibro Animal Health Corporation. Phibro Animal Health Corporation, Newark, NJ 07102.

Net Weight: 2 kg

101-8404-01B

c) add a known quantity of fish feed into a mixer, d) add the PAQFLOR™ (florfenicol) and of mixture to the feed in the mixer, 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 PAQFLOR™ (florfenicol) Inclusion Rates for Preparation of Type C Medicated Feed

| Feeding Rate | Florfenicol Concentration in Feed | | Amount of PAQFLOR™ (florfenicol) per Ton of Feed | | Amount of Fish Medicated per Ton of Feed per 15-day Treatment Period |
|--------------|-----------------------------------|------|--|------|--|
| | % | lb | lb | lb | |
| 100% | 100% | 100% | 100% | 100% | 100% |
| 1 | 1 | 1 | 1 | 1 | 1 |
| 2 | 2 | 2 | 2 | 2 | 2 |
| 3 | 3 | 3 | 3 | 3 | 3 |
| 4 | 4 | 4 | 4 | 4 | 4 |
| 5 | 5 | 5 | 5 | 5 | 5 |

Feeding Directions: Feed at the rate indicated for 10 consecutive days. PAQFLOR™ (florfenicol) medicated feed should only be administered once during the 10-day treatment period. Feeding fish at a period of 10 days and changing florfenicol concentrations included in the fish feed will deliver the appropriate treatment dose. Caution: Feed containing PAQFLOR™ (florfenicol) should not be fed to fish for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating further course of therapy. The expiration date for WFD for PAQFLOR™ (florfenicol) must not exceed 6 months from the date of issuance. WFD for PAQFLOR™ (florfenicol) shall not be refilled.

Caution: Side effects, and side effects have been reported in animals treated with florfenicol. Not all adverse drug reactions are reported to FDA. It is not always possible to reliably estimate the adverse drug reactions or to establish a causal relationship to product exposure using this data alone.

When using florfenicol for the first time, you must follow the appropriate National Pollutant Discharge Elimination System (NPDES) permitting authority of your treatment and of the following information. Acute and chronic water quality benchmarks for the protection of freshwater aquatic life have been derived by EPA for florfenicol following EPA guidance for calculating the 10% water quality criteria for the Great Lakes System (2010 CLE 1.2, App. A). The acute benchmark water quality benchmark concentration is 2.16 mg/L, exposure to 10% of the 10-day LC50 (acute). The chronic benchmark water quality benchmark concentration is 0.23 mg/L, equivalent to the 10% water quality benchmark concentration. The 10% water quality benchmark concentration is not discharge limits, but may be used by the NPDES authority to derive such limits for the period. Additional environmental information on PAQFLOR™ and the benchmark values are available in an environmental assessment posted at <https://www.epa.gov/npdes/npdes-10-percent-water-quality-benchmark-values-for-aquatic-life>.

WARNING: Avoid inhalation, and exposure, and direct contact with skin or eyes. Operators mixing and handling PAQFLOR™ (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. Flush face, mouth, and throat with water. Seek medical attention. Keep out of reach of children. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

CONTACT INFORMATION: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Phibro Animal Health Corporation at 800-455-0334 or 908-296-0000. For additional information about adverse drug experience reporting, see <https://www.fda.gov/oc/ohrt>.

STORAGE CONDITIONS: Store at temperatures up to 25°C with excursions permitted to 4°C.

Phibro
ANIMAL HEALTH CORPORATION



PAQFLOR 2%G Black Label 101-8404-01B 11356C715.ind 1

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PAQFLOR

florfenicol powder

Product Information

Product Type

VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG

Item Code (Source)

NDC:66104-8101

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 |
| | | | | |
| Product Characteristics | | | | |
| Color | white | Score | | |
| Shape | | Size | | |
| Flavor | | Imprint Code | | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:66104-8101-1 | 2 kg in 1 POUCH | | |
| 2 | NDC:66104-8101-2 | 16 kg in 1 BOX | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| ANADA | ANADA200803 | | 11/14/2024 | |

Labeler - Phibro Animal Health (006989008)

Registrant - Phibro Animal Health (006989008)

Revised: 3/2025

Phibro Animal Health