

ROMET 30- sulfadimethoxine and ormetoprim powder PHARMAQ AS

ROMET 30

Sulfadimethoxine & Ormetoprim

Type A Medicated Article

For freshwater-reared salmonids (trout and salmon) and catfish

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 ingredients

Sulfadimethoxine 113.5 grams per pound (25%) ormetoprim 22.7 grams per pound (5%) in a carrier suitable for incorporation in feeds.

For use in manufacturing medicated feeds only

Indications

For control of furunculosis in freshwater-reared salmonids (trout and salmon) caused by *Aeromonas salmonicida* and of enteric septicemia of catfish caused by *Edwardsiella ictaluri* strains susceptible to the sulfadimethoxine and ormetoprim combination.

Preparation of medicated feeds

Establish the weight of fish to be treated and calculate the amount of feed needed per day according to fish size and water temperature. Calculate the amount of Romet® 30 required for medicating the feed at the rate of 16.7 g of Romet®30 per 100 kg (7.6 g of Romet® 30/100 lbs) of fish body weight per day.

Medication of feed before pelletizing or extruding

Thoroughly mix the calculated amount of Romet® 30 into the mash feed prior to pelletizing or extruding. Refer to the dosage table below for recommended levels of use.

Feed Intake of Fish as Percent (%) of Body Weight

1
2
3
4

Lbs of Romet® 30 per Ton of Feed

33.30
16.70
11.10
8.33

Medication of feed after pelletizing

Prepare a liquid slurry by suspending Romet® 30 in a 5% gelatin solution. Coat the pelleted fish feed with the slurry, which should be constantly agitated to ensure uniform suspension of the Romet® 30 during addition. As a general rule, 10 gallons of gelatin solution is required to coat 2000 lb (1T) of pellets. The coated pellets be allowed to dry prior to bagging. Do NOT top dress pellets with Romet® 30 in a vegetable or fish oil suspension.

Use/Feeding Directions

Administer medicated feed daily for five consecutive days to provide approximately 50 mg of active ingredients per kg (23 mg/lb) of live body of fish per day.

Storage

Store dry in closed bag at or below 25° C (77° F), excursions permitted to 37° C (99° F)

Caution

If fish show no improvement within 2 to 3 days, or if signs of disease reappear after termination of treatment, reevaluate management practices, diagnosis of outbreak and establish susceptibility of the bacterial isolate(s) to the drug.

Warning

Withdraw 42 days in freshwater-reared salmonids (trout and salmon) and 3 days in catfish before slaughter or release as stocker fish.

Labels for feeds containing Romet® 30 must contain appropriate indications, limitations and warnings as well as required feed ingredient information

Approved by FDA under NADA # 125-933

Marketed by

PHARMAQ

part of Zoetis

PHARMAQ AS

Skogmo Industriomrade

N-7863 Overhalla

Norway

US-4-6001 Net wt 50 LB (22.68 kg)

Take Time

Observe Label Directions

Made in USA

Package Label

ROMET®



30

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The coated pellets should be allowed to air dry prior to bagging.
Rebag and store under proper feed storage conditions.

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Distributed by
AquaTactics Fish Health
Kirkland, WA

PHARMAQ
part of **zgetis**



US-6-6001

Net wt 50 LB (22.68 kg)

ROMET 30

sulfadimethoxine and ormetoprim powder

Product Information

Product Type	VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:15331-0103
Route of Administration	Oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sulfadimethoxine (UNII: 30CPC5LDEX) (SULFADIMETHOXINE - UNII:30CPC5LDEX)	Sulfadimethoxine	113.5 g in 0.45 kg
Ormetoprim (UNII: M3EFS94984) (ORMETOPRIM - UNII:M3EFS94984)	Ormetoprim	22.7 g in 0.45 kg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15331-0103-1	22.68 kg in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NADA	NADA125933	11/26/1984	
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Labeler - PHARMAQ AS (730355380)

Establishment

Name	Address	ID/FEI	Business Operations
International Nutrition Inc		968200175	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Tianhe Pharmaceutical Co., Ltd.		421144690	api manufacture

Revised: 7/2023

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