

WORM AND PARASITES AQUARIUM CURE PROGRAM FRESH- praziquantel Prodibio SAS

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Worm & Parasites Aquarium Cure Program Fresh

INSTRUCTIONS

PRESENTATION

- PRODUCT NAME: Worms & Parasites Fresh

- ACTIVE INGREDIENTS

The vials A and B contain per mL:

- 40,00 mg of 2-(Cyclohexylcarbonyl)-1,2,3,6,7-11b-hexahydro-4Hpyrazino(2,1a)-isoquinolin-4-one (praziquantel)
- The BioDigest Start vial contains nitrifying and denitrifying living bacteria that have not been genetically modified.

- EXCIPIENTS

- Purified water
- Propylene glycol

- PHARMACEUTICAL FORM & CONTENTS

- 3 A vials containing 1.3 mL
- 2 B vials containing 1.5 mL
- 1 vial of BioDigest Start containing 1.1 mL

- MANUFACTURER

Vials A and B : product manufactured for PRODIBIO, under Good Manufacture Practices (GMP), by Aquarium Münster Pahlmeier GmbH, Galgheide 8, D-48291 Telgte, Allemagne

Vial of BioDigest Start : PRODIBIO 3, Allée des Maraîchers, 13013 Marseille France

USAGE

- THERAPEUTIC INDICATIONS

Product intended only for treatment of ornamental freshwater fish infested with skin worms (Gyrodactylus), gill worms (Dactylogyrus), or tapeworms (Cestodes). Visible symptoms are fish rubbing against the scenery (to get rid of the parasites) in the case of Gyrodactylus; increased respiration for Dactylogyrus; and weight loss despite normal food intake for Cestodes.

- DOSAGE AND DIRECTIONS FOR USE

Shake each vial well before use. Follow this protocol:

Aquarium Volume

Days	60-100L	101-180L
Day 1	Water change: - 75% of the volume Do not feed the fish Vials AAA together	Water change: - 75% of the volume Do not feed the fish Vials AAABB together
Day 2	Water change: - 50% of the volume Feed the fish No Treatment	Water change: - 50% of the volume Feed the fish No Treatment
Day 3	Feed the fish No Treatment	Feed the fish No Treatment
Day 4	Feed the fish No Treatment	Feed the fish No Treatment
Day 5	Feed the fish No Treatment	Feed the fish No Treatment
Day 6	Feed the fish No Treatment	Feed the fish No Treatment
Day 7	Do not feed the fish Vials BB at the same time	Feed the fish Water change: - 50% of the volume Add the vial BioDigest Start
Day 8	Water change: - 50% of the volume Feed the fish No Treatment	
Day 9	Water change: - 50% of the volume Feed the fish No Treatment Add the vial BioDigest Start	

During the treatment, carefully monitor the aquarium. Ensure a good water flow and a good oxygenation. Indeed, in the presence of a large bacterial population (filter, gravel), the use of Worms & Parasites Fresh can lead to significant bacterial growth which will induce over-consumption of oxygen. If the water becomes cloudy due to a sudden increase in the number of bacteria, or if signs of a lack of oxygen appear, do an immediate water change of 50% of the Aquarium Volume.

- PRESERVATION

Keep the vials in the original packaging away from direct sunlight and heat sources.
Do not use after the expiration date printed on the box and vials.

PRECAUTIONS

- CONTRAINDICATIONS & INTERACTIONS

Invertebrates such as snails and shrimps cannot withstand Worms & Parasites Fresh, and must be removed from the aquarium before beginning the treatment.

- UNWANTED SIDE EFFECTS

None known. Should you notice any side effects, please let us know (info@prodibio.fr).

Product for ornamental fish only, do not use with fish intended for consumption.

Keep out of the reach of children.

For animal treatment only

Package Labeling:



Bacteria & Fungi Fresh



Pour le traitement des animaux uniquement
For animal treatment only

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|---------------------------------------|--------------------------------------|
| - FR - NOTICE D'UTILISATION - 2 | - PT - INSTRUÇÕES DE UTILIZAÇÃO - 26 |
| - EN - INFORMATION OF USE - 6 | - EL - ΦΥΛΛΑ ΟΔΗΓΙΩΝ ΧΡΗΣΗΣ - 30 |
| - ESP - MANUAL DE UTILIZACIÓN - 10 | - PL - INSTRUKCJA UŻYCIA - 34 |
| - RU - РУКОВОДСТВА ПО ПРИМЕНЕНИЮ - 14 | - JA - 使用説明書 - 38 |
| - DE - GEBRAUCHSANWEISUNGEN - 18 | - ZH - 使用说明 - 42 |
| - NL - GEBRUIKSHANDLEIDING - 22 | |

- Bacteria & Fungi Fresh n'est pas toléré par les invertébrés, escargots et crevettes, qui doivent être retirés de l'aquarium avant le début du traitement.
- Invertebrates such as snails and shrimps cannot withstand Bacteria & Fungi Fresh, and must be removed from the aquarium before beginning the treatment.
- Bacteria & Fungi Fresh no es tolerado por los invertebrados, caracoles y camarones, que deben retirarse del acuario antes del inicio del tratamiento.
- バクテリア & フンギ・フレッシュは、無脊椎動物、カタツムリ、エビには適さないため、投薬開始前にこれらを水槽から出してください。
- 钉螺和虾等无脊椎动物不能承受Bacteria & Fungi Fresh的作用，在治疗之前应先将它们撤出。



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3, Allée des Maraîchers, 13013 Marseille France

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freshwater fish infested with skin worms (Gyrodactylus), gill worms (Dactylogyrus), or tapeworms (Cestodes). Visible symptoms are fish rubbing against the scenery (to get rid of the parasites) in the case of Gyrodactylus; increased respiration for Dactylogyrus; and weight loss despite normal food intake for Cestodes.

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- UNWANTED SIDE EFFECTS

None known. Should you notice any side effects, please

let us know (info@prodibio.fr).

- SPECIAL PRECAUTIONS

Keep out of the reach of children.

Product for ornamental fish only, do not use with fish intended for consumption.

Instructions update 2012-03-20.

WORM AND PARASITES AQUARIUM CURE PROGRAM FRESH

praziquantel kit

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86048-001
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86048-001-01	1 in 1 BOX		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 VIAL, SINGLE-USE	3.9 mL
Part 2	2 VIAL, SINGLE-USE	3 mL

Part 1 of 2

A VIAL

praziquantel solution

Product Information

Item Code (Source)	NDC:86048-002
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	40 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86048-002-01	1.3 mL in 1 VIAL, SINGLE-USE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2015	

Part 2 of 2	
B VIAL	
praziquantel solution	

Product Information	
Item Code (Source)	NDC:86048-011
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	40 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86048-011-01	1.5 mL in 1 VIAL, SINGLE-USE		

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

unapproved drug other		08/24/2015	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2015	

Labeler -
Prodibio SAS (647909431)