# WORM AND PARASITES AQUARIUM CURE PROGRAM SALT- 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.

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#### **Worm & Parasites Aquarium Cure Program Salt**

#### **INSTRUCTIONS**

#### **PRESENTATION**

- PRODUCT NAME: Worms & Parasites Salt

#### - 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 Pahlsmeier 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 <b>BioDigest Start</b>
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 <b>BioDigest Start</b>	

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.

Do not use with another treatment.

#### - UNWANTED SIDE EFFECTS

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

#### - SPECIAL PRECAUTIONS

Sources of UV radiation and skimmers must be stopped during the treatment. Product for ornamental fish only, do not use with fish intended for consumption.

Keep out of the reach of children.

## **Package Labeling:**



# Worms & Parasites Salt



Pour le traitement des animaux uniquement For animal treatment only

- FR NOTICE D'UTILISATION 2
- EN INFORMATION OF USE 6
- ESP MANUAL DE UTILIZACIÓN 10
- RU РУКОВОДСТВА ПО ПРИМЕНЕНИЮ 14
- DE GEBRAUCHSANWEISUNGEN 18
- NL GEBRUIKSHANDLEIDING 22

- PT INSTRUÇOES DE UTILIZAÇÃO 26
- EL ΦΥΛΛΑ ΟΔΗΓΙΩΝ ΧΡΗΣΗΣ 30
- PL INSTRUKCJA UŻYCIA 34
- JA 使用説明書 38
- ZH 使用说明 42
- Worms & Parasites Salt n'est pas toléré par les invertébrés, coraux, escargots, coquillages et crevettes, qui doivent être retirés de l'aquarium avant le début du traitement.
- Invertebrates such as corals, snails, seashells and shrimps cannot withstand Worms & Parasites Salt, and must be removed from the aquarium before beginning the treatment.
- Worms & Parasites Salt no es tolerado por los invertebrados, corales, caracoles, conchas y camarones, que deben retirarse del acuario antes del inicio del tratamiento.
- ウォーム & パラサイト・ソルトは、無脊椎動物、サンゴ類、カタツムリ、貝、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。
- 珊瑚、钉螺和虾等无脊椎动物不能承受Worms & Parasites Salt的作用,在治疗之前应先将它们从水箱中撤出。



## **WORMS & PARASITES SALT**

INSTRUCTIONS

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- EXCIPIENTS
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- PHARMACEUTICAL FORM & CONTENTS
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3, Allée des Maraîchers, 13013 Marseille France

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CONTRAINDICATIONS & INTERACTIONS
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- SPECIAL PRECAUTIONS

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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 SALT

praziquantel kit

#### **Product Information**

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:86048-003

Packaging	Pacl	kag	ing
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#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86048-003-01	1 in 1 BOX		

#### **Ouantity of Parts**

Quain	mility of Lurio		
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
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Route of Administration ORAL

## Active Ingredient/Active Moiety

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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: 6 DC9 Q167V3)			

P	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				
l	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ı	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)

Revised: 8/2015 Prodibio SAS