BACTERIA AND FUNGI AQUARIUM CURE PROGRAM SALT- acriflavine hydrochloride, methyl orange, ethacridine lactate, methylene blue anhydrous 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.

BACTERIA & FUNGI Aquarium Cure Program Salt

INSTRUCTIONS

PRESENTATION

- PRODUCT NAME: Bacteria & Fungi Salt

- ACTIVE INGREDIENTS

- ACTIVE INGREDIENTS

The vials A and B contain per mL:

• 2.00 mg of 3,6-diamino-10-methylacridinium chloride mixt. with 3,6-diaminoacridine (acriflavine chloride)

- 0.26 mg of 4-(4-dimethylaminophenylazo)-benzenesulfonate sodium salt (methyl orange)
- 4.00 mg of 6,9-diamino-2-ethoxyacridine-DL-lactate monohydrate (ethacridine lactate)

• 2.75 mg of 3,7-bis(dimethylamino)phenazathionium chloride (methylthionine chloride) 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 1.0 mL
- 1 vial of BioDigest Start containing 1.1 mL

- MANUFACTURER

Vials A and B : product manufactured for **PRODIBIO**, under GMP, by Aquarium Münster Pahlsmeier GmbH, Galgheide 8, D-48291 Telgte, GE Vial of BioDigest Start : **PRODIBIO** 3, Allée des Maraîchers, 13013 Marseille, France

USAGE

- THERAPEUTIC INDICATIONS

Product intended only for the treatment of ornamental saltwater fish. Bacteria & Fungi Salt has a wide spectrum of action and treats a large number of diseases caused by bacteria or fungi. Visible symptoms

may be whitish or yellowish secretions, ulcers, skin inflammations, bleeding, scale loss, fin decomposition, bulging eyes, cotton fluff, swollen belly, or unusual oscillatory movements of the fish. Bacteria & Fungi Salt can be used when the diagnosis of the disease is neither possible nor obvious.

- DOSAGE AND DIRECTIONS FOR USE

Shake each vial well before use. Follow this protocol:

Days	60-100L	101-180L
Day 1	Do not feed the fish Vial A	Do not feed the fish Vials AB together
Day 2	Do not feed the fish Vial B	Do not feed the fish Vials A
Day 3	Feed the fish No Treatment	Feed the fish No Treatment
Day 4	Do not feed the fish Vial A	Feed the fish No Treatment
Day 5	Do not feed the fish Vial B	Feed the fish No Treatment
Day 6	Feed the fish No Treatment	Feed the fish No Treatment
Day 7	Do not feed the fish Vial A	Do not feed the fish IVials AB at the same time
Day 8	Feed the fish No Treatment	Feed the fish No Treatment
Day 9	Water change: -50% of the Ivolume Feed the fish No Treatment Add the vial of BioDigest Start	Water Change: -30% of the volume Feed the fish INo Treatment Add the vial of BioDigest StartI

Ensure a good flow and good water oxygenation. To protect the biological filter, during the treatment days, remove the bacterial support material from the filter. Run it in another aquarium if possible, or at least keep it moist with water in a container. Reinsert the support material on the days the fish are fed, after briefly rinsing it with clean water.

- 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 corals, snails, anemones and shrimps cannot withstand Bacteria & Fungi Salt, and must be removed from the aquarium before beginning the treatment. The simultaneous use of water treatment products may decrease the effectiveness of Bacteria & Fungi Salt. Do not use with another treatment.

- UNWANTED SIDE EFFECTS

None known. Should you notice any side effects, please let us know (**info@prodibio.fr**). The water coloration is due to the active ingredients and will disappear after a few days.

- 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.

This veterinary medicines is marketed in accordinance with the Small Animal Exception Scheme Instructions update 2012-08.

- Special precautions for the disposal of unused pharmaceuticals

Dispose old drugs not entirely used up at the respective collecting points Disposal advice: after use, vials must be thrown in recyclable glass rubbish

Package Labeling:



Bacteria & Fungi Salt



Pour le traitement des animaux uniquement For animal treatment only

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- Bacteria & Fungi Salt n'est pas toléré par les invertébrés, coraux, anémones et crevettes, qui doivent être retirés de l'aquarium avant le début du traitement.

- Invertebrates such as corals, snails, anemones and shrimps cannot withstand Bacteria & Fungi Salt, and must be removed from the aquarium before beginning the treatment.

- Bacteria & Fungi Fresh no es tolerado por los invertebrados, corales, anémonas 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、サンゴ類、イソギンチャク、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、海葵和虾等无脊椎动物不能承受Bacteria & Fungi Salt 的作用,在治疗之前应先将它们撤出。





BACTERIA & FUNGI SALT

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Instructions update 2012-03-20.

BACTERIA AND FUNGI AQUARIUM CURE PROGRAM SALT

acriflavine hydrochloride, methyl orange, ethacridine lactate, methylene blue anhydrous kit

Produ	uct Information			
Produc	ct T yp e	OTC ANIMAL DRUG	Item Code (Source)	NDC:86048-010
Packa	ging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:	86048-010-01	1 in 1 BOX		
Quant	tity of Parts			
Part #	Pac	kage Quantity	Total Product	Quantity
Part 1	3 VIAL, SINGLE-US	E	3.9 mL	
Part 2	2 VIAL, SINGLE-US	E	2.0 mL	

Part 1 of 2

A VIAL

acriflavine hydrochloride, methyl orange, ethacridine lactate, methylene blue anhydrous solution

Product Information	n						
Item Code (Source)		NDC:86048-009					
Route of Administration	n	ORAL					
Active Ingredient/A	ctive Moie	ety					
	In	gredient Name			Basi Stre		Strength
ACRIFLAVINE HYDRO CI	HLORIDE (U	NII: 1S73VW819C) (ACRIFLA	VINE - UNII	:1T3A50395T)	ACRIFLA	VINE	2.00 mg in 1 mL
METHYL ORANGE (UNII:	6B4TC34456	5) (METHYL ORANGE - UNII:	6B4TC3445	6)	METHYL (ORANGE	0.26 mg in 1 mL
ethacridine lactate (UNII	: V5IL571C1T) (ETHACRIDINE - UNII:WIX8	35M1A6R)		ethacridin	e lactate	4.00 mg in 1 mL
METHYLENE BLUE ANH UNII:T42P99266K)	YDROUS (UN	NII: 8NAP7826UB) (METHYL	ENE BLUE -		METHYLE	NE BLUE	2.75 mg in 1 mL
Inactive Ingredients	5						
		Ingredient Name				S	trength
WATER (UNII: 059QF0KO	0R)						U
PROPYLENE GLYCOL (U		167V3)					
Packaging							
# Item Code	Da	ckage Description	Marke	ting Start Da	to .	Markotin	g End Date
1 NDC:86048-009-01		VIAL, SINGLE-USE	Mai K	ting Start Da			g Liiu Date
Marketing Infor	mation						
Marketing Category	Applicatio	n Number or Monograph	Citation	Marketing S	tart Date	Marke	ting End Date
unapproved drug other				08/24/2015			
Part 2 of 2							
B VIAL							
acriflavine hydrochlori	de, methyl o	orange, ethacridine lacta	te, methyle	ene blue anhy	drous sol	ution	
Product Information	n						

Item Code	(Source)
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ORAL

Route of Administration

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACRIFLAVINE HYDRO CHLORIDE (UNII: 1S73VW819C) (ACRIFLAVINE - UNII:1T3A50395T)	ACRIFLAVINE HYDROCHLORIDE	2.00 mg in 1 mL
methyl orange (UNII: 6B4TC34456) (methyl orange - UNII:6B4TC34456)	methyl orange	0.26 mg in 1 mL
ethacridine lactate (UNII: V5IL571C1T) (ETHACRIDINE - UNII:WIX85M1A6R)	ETHACRIDINE	4.00 mg in 1 mL
METHYLENE BLUE ANHYDROUS (UNII: 8NAP7826UB) (METHYLENE BLUE - UNII:T42P99266K)	METHYLENE BLUE	2.75 mg in 1 mL

Inactive Ingredi	ents					
		Ingredient Name				Strength
WATER (UNII: 059QF	0 KO 0	R)				
PROPYLENE GLYCO	L (UN	NII: 6DC9Q167V3)				
Packaging						
# Item Code		Package Description	Marke	ting Start Date	N	Marketing End Date
1 NDC:86048-014-01		1.0 mL in 1 VIAL, SINGLE-USE				
		10 m2 m 1 + 112, 02 002 002				
Marketing Inf						
Marketing Inf	form		Citation	Marketing Start I	Date	Marketing End Date
•	form y 2	nation	Citation	Marketing Start I 08/24/2015	Date	Marketing End Date
Marketing Categor	form y 2	nation	Citation	-	Date	Marketing End Date
Marketing Categor	form y 2	nation	Citation	-	Date	Marketing End Date
Marketing Categor unapproved drug other	form y 2	1ation Application Number or Monograph	Citation	-	Date	Marketing End Date
Marketing Categor	form y 2	1ation Application Number or Monograph	Citation	-	Date	Marketing End Date
Marketing Categor unapproved drug other	Form y 2 Form	1ation Application Number or Monograph		-		Marketing End Date Marketing End Date

Labeler - Prodibio SAS (647909431)

Revised: 9/2015

Prodibio SAS