BACTERIA AND FUNGI AQUARIUM CURE PROGRAM FRESH- 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 Fresh

INSTRUCTIONS

PRESENTATION

-PRODUCT NAME: Bacteria & Fungi Fresh

- 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 freshwater fish. Bacteria & Fungi Fresh 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 Fresh 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 Vials 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 No Treatment Add the vial of BioDigest Start

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 snails and shrimps cannot withstand Bacteria & Fungi Fresh, and must be removed from the aquarium before beginning the treatment. Some filiform plants can be damaged by the treatment. The simultaneous use of water treatment products may decrease the effectiveness of Bacteria & Fungi Fresh. 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 Fresh



Pour le traitement des animaux uniquement For animal treatment only

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- Bacteria & Fungi Fresh n'est pas toléré par les invertébrés, escargots et crevettes, qui doivent être retirés de 'aquarium avant le début du traitement.
- Invertebrates such as snails and shrimps cannot withstand Bacteria & Fungi Fresh, and must be removed from the aguarium 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。





BACTERIA & FUNGI FRESH

INSTRUCTIONS

PRESENTATION

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The BioDigest Start vial contains nitrifying and denitrifying living bacteria that have not been genetically modified.

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- Propylene glycol

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- 2 B vials containing 1.0 mL
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- DOSAGE AND DIRECTIONS FOR USE Shake each vial well before use. Follow this protocol:

	Aquarium Volume			
Days	60-100L	101-180L		
Day 1	Do not feed the fish Vial A	Do not feed the fish Vials AB at the same time		
Day 2	Do not feed the fish Vial B	Do not feed the fish Vial 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 Vials AB at the same time		
Day 8	Feed the fish No Treatment	Feed the fish No Treatment		
Day 9	Water change: - 50% of the volume Feed the fish No Treatment Add the vial of BioDigest Start	Water change: - 30% of the volume Feed the fish No Treatment Add the vial of BioDigest Start		

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with water in a container, Keinsert 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

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The simultaneous use of water treatment products may decrease the effectiveness of Bacteria & Fungi Fresh.

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 must be stopped during the treatment.

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.

BACTERIA AND FUNGI AQUARIUM CURE PROGRAM FRESH

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

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:86048-008

Packaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:86048-008-01	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	2.0 mL	

Part 1 of 2

A VIAL

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

Product Information

Item Code (Source) NDC:86048-009

Route of Administration ORAL

Active Ingredient/Active Moiety Basis of **Ingredient Name** Strength Strength 2.00 mg ACRIFLAVINE HYDRO CHLO RIDE (UNII: 1S73VW819C) (ACRIFLAVINE - UNII:1T3A50395T) ACRIFLAVINE in $1\,mL$ 0.26 mg METHYL ORANGE (UNII: 6B4TC34456) (METHYL ORANGE - UNII:6B4TC34456) METHYL ORANGE in $1\,mL$ 4.00 mg ethacridine lactate (UNII: V5IL571C1T) (ETHACRIDINE - UNII:WIX85M1A6R) ethacridine lactate in $1\,\text{mL}$ METHYLENE BLUE ANHYDROUS (UNII: 8 NAP7826 UB) (METHYLENE BLUE -2.75 mg METHYLENE BLUE UNII:T42P99266K) in $1\,\text{mL}$

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:86048-009-01	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

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

Product Information

Item Code (Source)	NDC:86048-014
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACRIFLAVINE HYDRO CHLO RIDE (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 ANHYDRO US (UNII: 8NAP7826UB) (METHYLENE BLUE - UNII: T42P99266K)	METHYLENE BLUE	2.75 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:86048-014-01	1.0 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: 9/2015 Prodibio SAS