

**SPOTS AND VELVETS AQUARIUM CURE PROGRAM FRESH- acriflavine hydrochloride, gentian violet, malachite green oxalate, methylene blue**  
**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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**SPOTS & VELVETS Aquarium Cure Program FRESH**

**INSTRUCTIONS**

**PRESENTATION**

- PRODUCT NAME : Spots & Velvets Fresh

**- ACTIVE INGREDIENTS**

The vials A and B contain per mL:

- 0.3 mg of 3,6-Diamino-10-methylacridinium chloride mixt. with 3,6-diaminoacridine (acriflavine chloride)
- 0.5 mg of Hexamethylpararosaniline chloride (crystal violet)
- 1.0 mg of N,N,N',N'-Tetramethyl-4,4'-diaminotriphenylcarbenium oxalate (malachite green oxalate)
- 2.5 mg of 3,7-bis(Dimethylamino)phenazathionium chloride (methylene blue)

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 0.8 mL each
- 2 B vials containing 0.6 mL each
- 1 vial of BioDigest Start containing 1.1 mL each

**- 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 fish with the so-called "white spots" and "velvet" diseases, mainly caused by *Ichthyophthirius*, *Oodinium* and secondary bacterial infections caused indirectly by these protists. Visible symptoms are white spots, granular lesions or fluffy layers of pale

gray. They appear on the gills, fins and may extend to the whole body. Infected fish fins retract and try to remove the parasites by rubbing against the scenery. Those whose gills are very affected have an abnormally high respiratory activity, become apathetic and lose weight quickly.

#### - 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 <b>Vial A</b>	Do not feed the fish <b>Vials AB together</b>
Day 2	Do not feed the fish <b>Vial A</b>	Do not feed the fish <b>Vials AB together</b>
Day 3	Feed the fish No Treatment	Feed the fish No Treatment
Day 4	Do not feed the fish <b>Vial B</b>	Feed the fish No Treatment
Day 5	Feed the fish No Treatment	Feed the fish No Treatment
Day 6	Do not feed the fish <b>Vial A</b>	Do not feed the fish <b>Vial A</b>
Day 7	Do not feed the fish <b>Vial B</b>	Feed the fish No Treatment
Day 8	Feed the fish No Treatment	Feed the fish No Treatment
Day 9	Feed the fish Water change 50% of the volume- Add the vial <b>BioDigest Start</b>	Feed the fish Water change 30% of the volume Add vial <b>BioDigest Start</b>

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 Spots & Velvets 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 softened water may decrease the effectiveness of 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](mailto: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.**

Instructions update 2012-08.

This veterinary medicines is marketed in accordance with the Small Animal Exception Scheme

### **- Special precautions for the disposal of unused pharmaceuticals**

Dispose of drugs not entirely used up at the respective collecting points

Disposal advice: after use, vials must be thrown in recyclable glass rubbish

### **Package Labeling:**

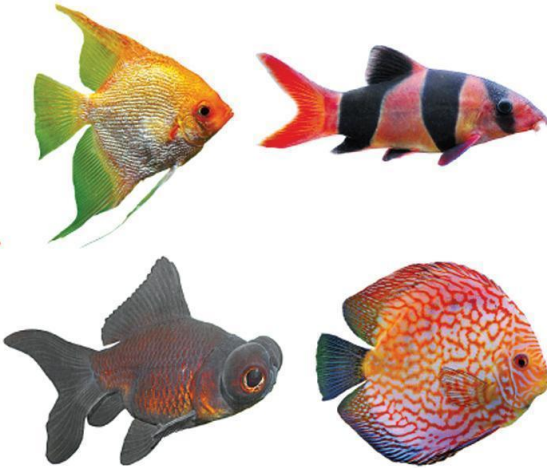


# Spots & Velvets

Aquarium Cure Program

FRESH

Soin des maladies velours et points blancs  
*Cure for velvets and white spots diseases*



Formule adaptée pour bacs de  
*Formula designed for tanks from*

60 L → 180 L (15 → 45 US gal)

PRODIBIO  
AQUARIUM CURE PROGRAM

# Spots & Velvets Fresh



Pour le traitement des animaux uniquement  
For animal treatment only

- |                                       |                                      |
|---------------------------------------|--------------------------------------|
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| - EN - INFORMATION OF USE - 6         | - EL - ΦΥΛΛΑ ΟΔΗΓΙΩΝ ΧΡΗΣΗΣ - 30     |
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| - NL - GEBRUIKSHANDLEIDING - 22       |                                      |

- Les invertébrés tels qu'escargots et crevettes ne supportent pas Spots & Velvets Fresh et doivent être retirés de l'aquarium avant de débuter le traitement.  
- Invertebrates such as snails and shrimps cannot withstand Spots & Velvets Fresh, and must be removed from the aquarium before beginning the treatment.  
- Los invertebrados como los caracoles y camarones no soportan Spots & Velvets Fresh y deben ser retirados del acuario antes de comenzar el tratamiento.  
- カタツムリやエビなどのような無脊椎動物には、スポット & ベルベット・フレッシュは適しません。投薬前にこれらの生き物は水槽から出してください。  
- 对钉螺和虾等无脊椎动物不能使用Spots & Velvets Fresh, 它们应该在治疗之前从水箱中撤出。



## SPOTS & VELVETS FRESH

### INSTRUCTIONS PRESENTATION

- PRODUCT NAME : Spots & Velvets Fresh
- ACTIVE INGREDIENTS  
The vials A and B contain per mL:
  - 0.3 mg of 3,6-Diamino-10-methylacridinium chloride mixt. with 3,6-diaminoacridine (acriflavine chloride)
  - 0.5 mg of Hexamethylpararosaniline chloride (crystal violet)
  - 1.0 mg of N,N,N',N'-Tetramethyl-4,4'-diaminotriphenyl-carbenium oxalate (malachite green oxalate)
  - 2.5 mg of 3,7-bis(Dimethylamino)phenazathionium chloride (methylene blue)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 0.8 mL each
- 2 B vials containing 0.6 mL each
- 1 vial of BioDigest Start containing 1.1 mL each

#### - MANUFACTURER

Vials A and B : product manufactured for PRODIBIO, under GMP, by Aquarium Münster Pahlmeier 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 fish with the so-called "white spots" and "velvet" diseases, mainly caused by *Ichthyophthirius*, *Oodinium* and secondary bacterial infections caused indirectly by these protists. Visible symptoms are white spots, granular lesions or fluffy layers of pale gray. They appear on the gills, fins and may extend to the whole body. Infected fish fins retract and try to remove the parasites by rubbing against the scenery. Those whose gills are very affected have an abnormally high respiratory activity, become apathetic and lose weight quickly.

##### - 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 together
Day 2	Do not feed the fish Vial A	Do not feed the fish Vials AB together
Day 3	Feed the fish No Treatment	Feed the fish No Treatment
Day 4	Do not feed the fish Vial B	Feed the fish No Treatment
Day 5	Feed the fish No Treatment	Feed the fish No Treatment
Day 6	Do not feed the fish Vial A	Do not feed the fish Vial A
Day 7	Do not feed the fish Vial B	Feed the fish No Treatment
Day 8	Feed the fish No Treatment	Feed the fish No Treatment
Day 9	Feed the fish Water change 50% of the volume- Add vial BioDigest Start	Feed the fish Water change 30% of the volume Add vial 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

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 Spots & Velvets 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 softened water may decrease the effectiveness of 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](mailto: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.

## SPOTS AND VELVETS AQUARIUM CURE PROGRAM FRESH

acriflavine hydrochloride, gentian violet, malachite green oxalate, methylene blue kit

### Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86048-004
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86048-004-01	1 in 1 BOX		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 VIAL, SINGLE-USE	2.4 mL
Part 2	2 VIAL, SINGLE-USE	1.2 mL

### Part 1 of 2

#### A VIAL

acriflavine hydrochloride, gentian violet, malachite green oxalate, methylene blue solution

Product Information	
Item Code (Source)	NDC:86048-005
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GENTIAN VIOLET (UNII: J4Z741D6O5) (GENTIAN VIOLET CATION - UNII:3GVJ31T6YY)	GENTIAN VIOLET	0.5 mg in 1 mL
MALACHITE GREEN OXALATE (UNII: GY1H9O33VU) (MALACHITE GREEN - UNII:12058M7ORO)	MALACHITE GREEN	1.0 mg in 1 mL
ACRIFLAVINE HYDROCHLORIDE (UNII: 1S73VW819C) (ACRIFLAVINE - UNII:1T3A50395T)	ACRIFLAVINE	0.3 mg in 1 mL
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	2.5 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:86048-005-01	0.8 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>B VIAL</b>
acriflavine hydrochloride, gentian violet, malachite green oxalate, methylene blue solution

Product Information	
Item Code (Source)	NDC:86048-012
Route of Administration	ORAL



Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ACRIFLAVINE HYDRO CHLORIDE (UNII: 1S73VW819C) (ACRIFLAVINE - UNII:1T3A50395T)			ACRIFLAVINE	0.3 mg in 1 mL
GENTIAN VIOLET (UNII: J4Z741D6O5) (GENTIAN VIOLET CATION - UNII:3GVJ31T6YY)			GENTIAN VIOLET	0.5 mg in 1 mL
MALACHITE GREEN O XALATE (UNII: GY1H9O33VU) (MALACHITE GREEN - UNII:12058M7ORO)			MALACHITE GREEN	1.0 mg in 1 mL
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)			METHYLENE BLUE	2.5 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:86048-012-01	0.6 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