

SPOTS AND VELVETS AQUARIUM CURE PROGRAM SALT- ethacridine lactate, 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](#).

SPOTS & VELVETS Aquarium Cure Program SALT

INSTRUCTIONS

PRESENTATION

-PRODUCT NAME : Spots & Velvets Salt

- ACTIVE INGREDIENTS

The vials A and B contain per mL:

- 0.10 mg of 6,9-Diamino-2-ethoxyacridine-DL-lactate monohydrate (ethacridine lactate)
- 0.05 mg of Hexamethylpararosaniline chloride (crystal violet)
- 1.25 mg of N,N,N',N'-Tetramethyl-4,4'-diamino triphenylcarbenium oxalate (malachite green oxalate)
- 0.10 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 1.6 mL
- 2 B vials containing 1.2 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 fish with the so-called "white spots" and "velvet" diseases, mainly caused by *Oodinium ocellatum*, *Cryptobia*, *Cryptocaryon*... Visible symptoms are fluffy layers of gray / light gray, or tiny white spots on the gills, fins and the rest of the body in later stages of the infection. Sick fish breathe heavily and with difficulty; they spread their gills wide.

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

Spots & Velvets Salt is well tolerated by invertebrates, and it is not necessary to remove corals from the aquarium during the treatment. Ensure a good water flow and a good 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

The simultaneous use of water treatment products may decrease the effectiveness of Spots & Velvets 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 medicine is marketed in accordance with the Small Animal Exception Scheme Instructions update 2012-08.

- 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 Salt



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 |
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| - NL - GEBRUIKSHANDLEIDING - 22 | |

- Spots & Velvets Salt est bien toléré par les invertébrés, il n'est pas nécessaire de retirer les coraux de l'aquarium pour la durée du traitement.

Spots & Velvets Salt is well tolerated by invertebrates, and it is not necessary to remove corals from the aquarium during the treatment.

- Spots & Velvets Salt es bien tolerado por los invertebrados, tampoco es necesario retirar los corales del acuario durante el tratamiento.

- 「スポット&ベルベット・ソルト」は無脊椎動物にも害がないため、投薬期間中に水槽内のサンゴ類を取り出す必要はありません

- S & V Salt不会影响无脊椎动物，也不需要治疗期间撤出水箱中的珊瑚。请保证水的良好循环和含氧量。



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- EXCIPIENTS

- Purified water
- Preservative agent

- Propylene glycol

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- 3 A vials containing 1.6 mL
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Aquarium Volume		
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Day 6	Feed the fish No Treatment	Feed the fish Water change: 30% of the volume Add the vial BioDigest Start
Day 7	Do not feed the fish Vial A	-
Day 8	Feed the fish No Treatment	-
Day 9	Feed the fish Water change 50% of the volume Add the vial BioDigest Start	-

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- CONTRAINDICATIONS & INTERACTIONS

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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

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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.

SPOTS AND VELVETS AQUARIUM CURE PROGRAM SALT

ethacridine lactate, gentian violet, malachite green oxalate, methylene blue kit

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86048-006
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86048-006-01	1 in 1 BOX		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 VIAL, SINGLE-USE	4.8 mL
Part 2	2 VIAL, SINGLE-USE	2.4 mL

Part 1 of 2

A VIAL

ethacridine lactate, gentian violet, malachite green oxalate, methylene blue solution

Product Information	
Item Code (Source)	NDC:86048-007
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	0.05 mg in 1 mL
MALACHITE GREEN OXALATE (UNII: GY1H9O33VU) (MALACHITE GREEN - UNII:12058M7ORO)	MALACHITE GREEN	1.25 mg in 1 mL
ETHACRIDINE LACTATE (UNII: V5IL571C1T) (ETHACRIDINE - UNII:WIX85M1A6R)	ETHACRIDINE	0.10 mg in 1 mL
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	0.10 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:86048-007-01	1.6 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	

Part 2 of 2
B VIAL
ethacridine lactate, gentian violet, malachite green oxalate, methylene blue solution

Product Information	
Item Code (Source)	NDC:86048-013
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ETHACRIDINE LACTATE (UNII: V5IL571C1T) (ETHACRIDINE - UNII:WIX85M1A6R)			ETHACRIDINE	0.10 mg in 1 mL
GENTIAN VIOLET (UNII: J4Z741D6O5) (GENTIAN VIOLET CATION - UNII:3GVJ31T6YY)			GENTIAN VIOLET	0.05 mg in 1 mL
MALACHITE GREEN OXALATE (UNII: GY1H9O33VU) (MALACHITE GREEN - UNII:12058M7ORO)			MALACHITE GREEN	1.25 mg in 1 mL
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)			METHYLENE BLUE	0.10 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:86048-013-01	1.2 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