PROTOMOR- malachite green oxalate, ethacridine lactate, methylene blue anhydrous, gentian violet solution

Aquarium Muenster Pahlsmeier GmbH

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.

Protomor

Information and directions on the use of protomor

Pharmaceutical company and manufacturer

Aquarium Münster Pahlsmeier GmbH Galgheide 8 D-48291 Telgte (Germany)

Name of the pharmaceutical product

protomor solution

Applications

Medication for ornamental fish against skin parasites, such as Oodinium ocellatum (coral fish disease), Cryptobia, Brooklynella, Trichodina and Cryptocarion. Visible symptoms include pale grey to dark, velvet-like films and barely visible spots which spread to the gills, fins and the entire body as the infection progresses. The gills stick out and the affected fish exhibit an increased breathing rate to the point of respiratory distress.

Types and quantities of active substances:

1 ml of solution contains: 1.25 mg Malachite green oxalate 0.10 mg Ethacridine lactate monohydrate 0.10 mg Methylthionine chloride 0.05 mg Methylrosaniline chloride

Contraindications and side effects

None known. Should you notice side effects in your ornamental fish, please inform your vet or pharmacist.

Species

Ornamental fish

Dosage and method of administration

protomor has no adverse effects on invertebrates and aquatic plants. Corals and anemones need not be excluded from the treatment. Shake well before use.

Day 1: Add 40 drops (= 2 ml) of protomor to the aquarium for each 100 l of water and stir to distribute. Do not feed the fish. Switch off protein skimmer and ultraviolet light system. Remove the

filter from the aquarium and place it over a container to continue running in order to keep the microorganisms in the filter. Oxygenate the aquarium water. If the water cannot be oxygenated without operating the filter then we recommend running the filter without filtration media in order to ensure sufficient water circulation. In this case keep the filtration media in a container with plenty of aquarium water.

Day 2: Add 20 drops (= 1 ml) of protomor to the aquarium for each 100 l of water and stir to distribute. Do not feed the fish.

Day 3: Do not add any medication to the water. Feed the fish as normal. Put the filter and, where applicable, the protein skimmer and ultraviolet light system back into operation. If the filtration media has been stored separately then the water must not be put back in the aquarium. In this case partially wash the filtration media out with lukewarm saltwater (not too thoroughly in order to retain some of the microorganisms) and put back in the filter.

Day 4: Add 40 drops (= 2 ml) of protomor to the aquarium for each 100 l of water and stir to distribute. Do not feed the fish. Switch off protein skimmer and ultraviolet light system. Remove the filter from the aquarium and place it over a container to continue running in order to keep the microorganisms in the filter. Oxygenate the aquarium water. If the water cannot be oxygenated without operating the filter then we recommend running the filter without filtration media in order to ensure sufficient water circulation. In this case keep the filtration media in a container with plenty of aquarium water.

Day 5: Do not add any medication to the water. Feed the fish as normal. Put the filter and, where applicable, the protein skimmer and ultraviolet light system back into operation. If the filtration media has been stored separately then the water must not be put back in the aquarium. In this case partially wash the filtration media out with lukewarm saltwater (not too thoroughly in order to retain some of the microorganisms) and put back in the filter.

Day 6: Do not add any medication to the water. Feed the fish as normal. Replace approx. 30 % of the aquarium water with purified saltwater.

Special precautions for storage

- Keep protomor out of direct light. Store in its original packaging.
- Keep out of reach of children.

Special warnings

- Do not administer to creatures which are used for human consumption.
- The water will change colour due to the active agents but will return to normal again after a few days.
- Do not use after the expiry date.

Special precautions for the disposal of unused pharmaceuticals

Take unused medical products and unfinished containers of medical products to the designated collection points.

Product Label





potocarion, etc.) and the associated bacterial infections Symptoms: Whitish- grey to dark velvet-like coatings with hardly visible dots. Types and quantities of active

substances 1 ml of solution contains: 1.25 mg Malachite green oxalate 0.10 mg Ethagridine lactate monohydrate

Aquarium Münster Pahlsmeier Gmb H D-48291 Telgte (Germany) Species: om am en tal fish Method of administration : Solution to be added to a quarium water Special precautions for the disposal of unused pharmaceuticals: Take unused medical products and unfinished containers of medical products to the designated collection points. Dosage form : Solution Keep out of reach of children. For veterinary use. Do not administer to animals that are for human consumption. Do not use after the expiry date. Protect protom or from light.

(FR) Traitement contre les protozoaires (Oodinium, Chilod on ella, Ichthyobod o. Trichodina . Cryptocarion . et c) et les infections bacteriennes secon daires Sympt ôm es : Suivants u ne peau d'une couleur allant du gris pale à foncé à l'aspect velouteux et de petits points à peine visibles. Composition des substances actives : 1ml desolution contient: 1,25 mg Malachitvert oxalate 0,10 mg de la ctate d'éthacridine mono-0,10 mg Chlorure methyl thionine 0,05 mg Chlorure methylrosaniline Entrepreneur et fabricant pharmaœu-

Aquarium Münster Pahlsmeier Gmb H Galgheide 8 D-48291 Tel gte (Allemagne)

Espèces a nimal e : poiss ons d'om em en ts Mode d'emploi : Solution à ajouter dans l'eau d'aquarium Précautions particulières à prendre pour l'élimin ation de médicaments

non utilisés :

Remettre les médicaments non utilisés aux points de collecte prévus à œt effet. Forme posologique : Solution Contenue : 100 ml Consignes particulières: Ne pas laisser à la portée des enfants. Pour an imaux . Ne pas administrer aux ani maux destinés à l'alimentation. Ne pas dépasser la date limite d'utilisation . Protéger protom or des rayons lumineux. À conserver dans l'emballage d'origine.

ES Medicamento para peces de acuario contra las enfermedades que producen coloracion es de la piel, tales como por ejemplo oodinium ocellatum (enfermed ad de peces de coral), cryptobia, brookly nella, trichodina y cryptocarion. Síntomas: Las características visibles se manifiestan en forma de recubrimientos aterciopela dos de color gris claro hasta tonos oscuros o puntos apenas visibles, los cual es se extienden en un estadio posterior a branquias, aletas y al resto del cuerpo. Las branquias se en sanchan y el p ez muestra un a frecuencia de respiración el evada e in duso asfixia. Tipo y can tidad de in grediente activo: 1 ml desolución contiene 1,25 mg de Verde de mal aquita 0,10 mg de Monohidrato de lactato de eta oridina Q10 mg de Cloruro de metil tioninio 0.05 mg de Cloruro de methylrosani lina Empresa farma céutica y fabricante: Aquarium Münster Pahlsmeier GmbH Galgheide 8 D-48291 Telgte (Alemania) Clase de animal: Pe ces de acuario Modo de empleo: Solución para la adición de aqua Medidas de precaución especiales para la el iminación de medicamentos no ut izados: Entre gar los medicamentos no consumidos en los lugares de recogida corre spondientes. La forma de dos ificación: Solución Contenido: 100 ml Advertencias especiales: Mantener fuera del alcance de los niños. Para los animales. No utilizar en animales destina dos al consumo human o. No utilizar una vez vencida la fecha de caducidad. proteger protomor de la luz. Guardar en el embalaje original.

Information and directions on the use of protomor

Pharmaceutical company and manufacturer

Aquarium Münster Pahlsmeier GmbH Galgheide 8 D-48291 Telgte (Germany)

Name of the pharmaceutical product

protomor solution

Applications

Medication for ornamental fish against skin parasites, such as Oodinium ocellatum (coral fish disease), Cryptobia, Brooklynella, Trichodina and Cryptocarion. Visible symptoms include pale grey to dark, velvet-like films and barely visible spots which spread to the gills, fins and the entire body as the infection progresses. The gills stick out and the affected fish exhibit an increased breathing rate to the point of respiratory distress.

Contraindications and side effects

None known. Should you notice side effects in your ornamental fish, please inform your vet or pharmacist.

Species

Ornamental fish

Dosage and method of administration

protomor has no adverse effects on invertebrates and aquatic plants. Corals and anemones need not be excluded from the treatment. Shake well before use.

- Day 1: Add 40 drops (= 2 ml) of protomor to the aquarium for each 100 l of water and stir to distribute. Do not feed the fish. Switch off protein skimmer and ultraviolet light system. Remove the filter from the aquarium and place it over a container to continue running in order to keep the microorganisms in the filter. Oxygenate the aquarium water. If the water cannot be oxygenated without operating the filter then we recommend running the filter without filtration media in order to ensure sufficient water circulation. In this case keep the filtration media in a container with plenty of aquarium water.
- Day 2: Add 20 drops (= 1 ml) of protomor to the aquarium for each 100 l of water and stir to distribute. Do not feed the fish.
- Day 3: Do not add any medication to the water. Feed the fish as normal. Put the filter and, where applicable, the protein skimmer and ultraviolet light system back into operation. If the filtration media has been stored separately then the water must not be put back in the aquarium. In this case partially wash the filtration media out with lukewarm saltwater (not too thoroughly in order to retain some of the microorganisms) and put back in the filter.
- Day 4: Add 40 drops (= 2 ml) of protomor to the aquarium for each 100 l of water and stir to distribute. Do not feed the fish. Switch off protein skimmer and ultraviolet light system. Remove the filter from the aquarium and place it over a container to continue running in order to keep the microorganisms in the filter. Oxygenate the aquarium water. If the water cannot be oxygenated without operating the filter then we recommend running the filter without filtration media in order to ensure sufficient water circulation. In this case keep the filtration media in a container with plenty of aquarium water.
- Day 5: Do not add any medication to the water. Feed the fish as normal. Put the filter and, where applicable, the protein skimmer and ultraviolet light system back into operation. If the filtration media has been stored separately then the water must not be put back in the aquarium. In this case partially wash the filtration media out with lukewarm saltwater (not too thoroughly in order to retain some of the microorganisms) and put back in the filter.
- Day 6: Do not add any medication to the water. Feed the fish as normal. Replace approx. 30 % of the aquarium water with purified saltwater.

Special precautions for storage

Voon protomor out of direct light. Ctore in its original packaging

- reep protomor out of direct light. Store in its original packaging.
- Keep out of reach of children.

Special warnings

- Do not administer to creatures which are used for human consumption.
- The water will change colour due to the active agents but will return to normal again after a few days.
- Do not use after the expiry date.

Special precautions for the disposal of unused pharmaceuticals

Take unused medical products and unfinished containers of medical products to the designated collection points.

Date of last revision of package insert

20/04/2015

PROTOMOR

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

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86052-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MALACHITE GREEN O XALATE (UNII: GY1H9O33VU) (MALACHITE GREEN CATION - UNII:AWT9R95TV1)	MALACHITE GREEN OXALATE	1.25 mg in 1 mL	
ETHACRIDINE LACTATE (UNII: V5IL571C1T) (ETHACRIDINE - UNII:WIX85M1A6R)	ETHACRIDINE LACTATE	0.10 mg in 1 mL	
METHYLENE BLUE ANHYDROUS (UNII: 8NAP7826UB) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	0.10 mg in 1 mL	
GENTIAN VIOLET (UNII: J4Z741D6O5) (GENTIAN VIOLET CATION - UNII:3GVJ31T6YY)	GENTIAN VIOLET	0.05 mg in 1 mL	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		03/23/2020		

Labeler - Aquarium Muenster Pahlsmeier GmbH (317318368)

Establishment

Name	Address	ID/FEI	Business Operations
Sigma-Aldrich Production GMBH		480945463	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Merck KGaA		342249299	api manufacture

Revised: 3/2020

Aquarium Muenster Pahlsmeier GmbH