DACTYMOR- praziquantel 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.

DACTYMOR

Information and directions on the use of dactymor (active agent: praziquantel)

Pharmaceutical company and manufacturer

Aquarium Münster Pahlsmeier GmbH Galgheide 8 D-48291 Telgte Germany

Name of the pharmaceutical product

dactymor solution (active agent: praziquantel)

Applications

Treatment against skin worms (Gyrodactylus), trematodes (Dactylogyrus) and tapeworms (Cestodes) in ornamental fish of the orders Cypriniformes, Perch, Catfish and live bearers in fresh water and marine water. Trematode infestation results in an increased respiratory rate. Ornamental fish with tapeworms frequently lose weight rapidly despite normal eating habits. Skin worm infestation will cause fish to attempt to rid themselves of the parasites by scraping.

Types and quantities of active substances:

1 ml of solution contains:

40 mg of Praziquantel

Contraindications and side effects

No known contraindications or side effects. Should you notice side effects in your ornamental fish, please inform your vet or pharmacist.

Species

Ornamental fish of the orders Cypriniformes, perch, catfish and live bearers

Dosage instructions and method of administration

Replace 3/4 of the aquarium water prior to beginning treatment with dactymor. Add 5

ml (= 100 drops) of dactymor for every 100 l of aquarium water and stir the aquarium water to disperse the product. Switch off UV-lamps. After 6 hours treatment a replacement of minimum 3/4 of the aquarium water is required. On the following day change half of the aquarium water. A single treatment is generally adequate for skin worms and tapeworms. However, trematode eggs are not affected. Therefore, when treating trematodes, the treatment should be repeated twice, waiting approx. one week between each treatment (for coldwater ornamental fish, wait approx. one-and-one-half weeks between treatments).

The aquarium should be continuously monitored during the treatment with dactymor. In aquariums containing a large biomass (microorganisms in filters, ground, etc.) the use of dactymor may result in an increase in bacterial growth. In turn this can lead to an oxygen depletion. Immediately change the aquarium water if signs of bacterial turbidity or indications of oxygen depletion are observed.

Special precautions for storage

- Protect dactymor from light. Store in its original packaging.
- Keep out of reach of children.

Special Warnings

- dactymor is unsuitable for invertebrates. Snails, mussels, shrimps, etc. must be excluded from the treatment.
- For ornamental fish of the orders Cypriniformes, perch, catfish and live bearers. Do not use on creatures which are used to obtain food.
- Do not use after the expiry date.

For veterinary use. Do not administer to animals that are for human consumption. Do not use after the expiry date. Protect dactymor from light. Store in the original package.

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 2012-12-20

product labling











Ch.-B.:/Lot no.: Lot no.:/Lote no:

Verwendbar bis:/Best before: à utiliser avant:/Consumir antes de: Aquarium Münster Pahlsmeier GmbH Galgheide 8 D-48291 Telgte (Germany)

Arzneimit tel für Zier fische gegen Hautwürm er (Gyrodactylus), Kiemenwürmer (Dactylogyrus) und Bandwürmer (Cestoden) Symptome: Bei Befallmit Kiemenwürmern erhöhte Atemfrequenz. Zierfische mit Bandwurm befall magern oft trot z normal em Fressverhalten rapide ab. Bei einem Befall mit Haut würmern versuchen die Fische, sich durch Scheuerbewegungen Wirkstoffe nach Art und Menge: 1 ml Lösung ent hält

40 mg Praziquante Pharmazeutischer Unternehmer und Hersteller: Aquarium Münster Pahlsmeier GmbH

Galgheide 8 D-48291 Telgte (Germany) Tierart: 7ierfische Art der Anwendung:

Lösung zum Zugeben zum Aguarien wasser Besondere Vorsichtsmaßnahmen für die Beseit ig ung von nicht verwendeten Armeimitteln:

Nicht aufgebrauch te Arzneimittel bei den en tsprechenden Sam melstellen ab geben. Darreichungsform: Lösung Inhalt: 20 ml

Besondere Hinweise: Arzneimittel für Kinderunzugänglich au fbewahren, Für Tiere, Nichtbei Tieren anwenden, die der Gewinnung von Lebensmitteln dienen. Nach Ablauf des Verfalldatums nicht mehr anwenden. dactymor vor Licht schützen. In der Originalverpackung aufbewahren.

GB Treatmentfor ornamental fish against skin worms (Gyrodactylus), trematodes (Dactylogyrus), and tapeworms (Cestoidean)

Sympt oms: Tiem atode in festation results in an increased respiratory rate. Ornamental fish with tapeworms frequently lose weight rapidly despite normal eating habits. Skin worm infestation will cause fish to attempt to rid themselves of the parasites

by scraping. Types and quantities of active substances: 1 ml of solution contains: 40 mg of Praziquantel

Pharm aceutical com pany and Man uf act urer:

Aquarium Münster Pahlsmeier GmbH D-482 91 Telate (Germany) Species: or namental fish Method of administration: Solution to be added to aquarium 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 Content: 20 ml Special hints:

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 dactymor from light. Store in the original package.

Traitement pour les poissons d'ornement con tre les vers de la peau (Gypod actyl us), les vers branchiaux (Dac tylo gyrus) et les vers plats (cestodes)

Sym ptômes: En cas de contamination des poissons d'ornement par de Dactylo gyrus, la fréquence respirato ire augmente. Les poissons d'ornement contaminés par æsto des maigrissent souvent rapi dement malgré une ingestion de nourriture normale. En cas decontamination par Gyrodact ylus, les poissons essayent de se débarrasser des vers en se frot tant. Composition: 1 m l de so lution contient:

40 mg de Praziquantel Entrepreneur et fabricant pharmaceut igue : Aquarium Münster Pahlsmeier GmbH

D-482 91 Telgte (Allemagne) Espèces animale: poissons d'ornements Mode d'emploi: Solution à ajouter dans l'éau d'aquarium

Précautions particulières à prendre pour l'élimination de médicaments non utilis és : Remettre les médicaments non utilisés aux

points de col lecte prévus à cet effet. Forme posolo gique : Solution Contenue: 20 ml

Consignes part iculières: Ne pas laisser à la portée des enfants. Pour animaux. Ne pas administrer aux animaux destinés à l'alimentation. Ne pas dépasser la date limite d'utilisation. Protéger dactymor des rayons lumineux. À conserve dans l'emballage d'origine.

peces ornament ales de las órdenes Cypriniformes, perca, bagre y olominas de agua dulce y salada contra lombrices de la piel (gyrodactylus), lombrices branquiales (dactylogyrus)y tenias (cestodos).

Síntomas: En caso de lombrices branquiales, la frecuencia respiratoria se incrementará. Los peœs de acuario con tenias sufren a menu-do una pérdida de peso a pesar de comer con normalidad. En el caso de lo mbrices de la piel, los peces intentan librarse de éstas

rozando sus cuerpos contra objetos. Tipo y cantidad de ingrediente activo: 1 ml de solución contiene 40 mg Praziquantel Empresaf ar macéu ticay fabricante: Aguarium Münster Pahlsmeier GmbH D-48291Telgte (Alemania) Clase deanimal: Peres deacuario Modo de empleo: Solución para la adición deagua Medidas de pre ca ución especia les para la eliminación de medicamentos no utilizados

Entregar los medicamentos no consumidos en los lugares de recogida correspondientes. La forma de dosificación: Solución Contenido: 20 ml

Advertenci as e speciales: Mantener fuera del alcance de los niños. Para los animales. No utilizar en animales destinados al consumo humano. No utilizar un a vez vencida la fecha de caducidad. proteger d'actymor de la luz. Guardaren el emb alaje original.





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Pharmaceutical company and manufacturer

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Applications

Treatment against skin worms (Gyrodactylus), trematodes (Dactylogyrus) and tapeworms (Costados) in arramantal fish of the arders Cunviniformes Darch Catfish and live hearers in

fresh water and marine water. Trematode infestation results in an increased respiratory rate. Ornamental fish with tapeworms frequently lose weight rapidly despite normal eating habits. Skin worm infestation will cause fish to attempt to rid themselves of the parasites by scraping.

Contraindications and side effects

No known contraindications or side effects. Should you notice side effects in your ornamental fish, please inform your vet or pharmacist.

Species

Ornamental fish of the orders Cypriniformes, perch, catfish and live bearers

Dosage instructions and method of administration

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Special precautions for storage

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Special warnings

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Special precautions for the disposal of unused pharmaceuticals

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Date of last revision of package insert

2012-12-20

DACTYMOR

praziquantel solution

Droc	luc+	Inform	ation
Proc	IUCL	Iniom	iation

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:86052-002

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457) PRAZIQUANTEL 10 mg in 1 mL

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86052-002-01	1 in 1 CARTON		
1		20 mL in 1 BOTTLE, GLASS		
2	NDC:86052-002-02	1 in 1 CARTON		
2		100 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Application Number or Monograph Marketing Start	
Category Citation Number of Monograph Marketing Start Date	Marketing End Date
unapproved drug other 03/19/2020	

Labeler - Aquarium Muenster Pahlsmeier GmbH (317318368)

Establishment

Name	Address	ID/FEI	Business Operations		
Alvira Animal Health LTD.		650916617	api manufacture		

	Esta	blis	shn	nent
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Name	Address	ID/FEI	Business Operations

Merck KGaA 342249299 api manufacture

Establishment				
Name	Address	ID/FEI	Business Operations	
Aquarium Muenster Pahlsmeier GmbH		317318368	manufacture	

Revised: 4/2024 Aquarium Muenster Pahlsmeier GmbH