

PRAZIMED- praziquantel powder

KDG Impresa LLC, Aqion

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.

Prazi-Med

Prazi-Med insert

PRAZI-MED™
(praziquantel powder for immersion)
For use in ornamental finfish, except
Callichthyidae and *Clariidae* catfish

LEGAL STATUS -- In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED – MIF 900-054. Extra-label use is prohibited.

THIS PRODUCT IS NOT TO BE USED IN ANIMALS INTENDED FOR USE AS FOOD FOR HUMANS OR FOOD-PRODUCING ANIMALS.

It is a violation of federal law to use this product in a manner other than as directed in the labeling.

USES: PRAZI-MED™ (praziquantel powder for immersion) is used for the treatment of internal parasites (flukes and tapeworms) and external parasites (flukes) susceptible to praziquantel in ornamental finfish, except *Callichthyidae* and *Clariidae* catfish.

PRAZI-MED™ is for use only in personal home aquariums, personal home ponds, or public aquariums and zoos.

DESCRIPTION: PRAZI-MED™ is a white, slightly soluble crystalline powder that contains the anti-cestode and anti-trematode compound, praziquantel. Praziquantel's mechanism of action is believed to be related to disruption of calcium homeostasis through interaction with voltage-gated calcium (Ca²⁺) channels within cells of the tegument of susceptible parasites (Baser et al., 2018).

WARNINGS:

USER SAFETY WARNINGS: Not for use in humans. Keep out of reach of children. Use in well-ventilated area and avoid inhalation. Avoid dust formation. Wear eye protection, dust mask, and chemical-resistant gloves when handling the drug. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, using tobacco products, or using the toilet.

INHALATION:

If inhaled and breathing becomes difficult, move victim to fresh air. Seek medical attention.

INGESTION:

If ingested: If the person is conscious, rinse mouth out with water and then drink plenty of water. Seek medical attention.

EYE CONTACT:

If in eyes: Rinse eye immediately with water for at least 15 minutes. If symptoms occur, seek medical attention.

SKIN CONTACT and/or CLOTHING CONTAMINATION:

Wash skin with soap and water, and launder clothing with detergent. If symptoms occur, seek medical attention.

ANIMAL SAFETY WARNINGS:

Some fish species may have increased sensitivity to the drug. Due to species sensitivity, do not use PRAZI-MED™ in catfish species of the *Callichthyidae* and *Clariidae* families. When fish species sensitivity levels are unknown, shorter duration of application is recommended. Ensure adequate aeration during treatment. Use the product with caution when dosing aquarium systems containing freshwater or marine invertebrate species or plants. The effectiveness of PRAZI-MED™ may vary depending on water conditions (pH, temperature, etc.), duration of treatment, and life stage/life cycle of the target parasite species.

ADDITIONAL RECOMMENDATIONS:

Handle in accordance with good hygiene and safe practices. Keep product and empty container away from heat and sources of ignition.

DIRECTIONS FOR USE:

PRAZI-MED™ may be added directly to your tank or pond by following the instructions below.

Day 1

- Before using PRAZI-MED™, discontinue the use of protein skimmers, and remove chemical filtration and/or activated carbon in the aquarium or pond during the treatment period.
- PRAZI-MED™ is packaged as a soluble powder and must be mixed with water to make a concentrated stock solution prior to use.
 - To make a concentrated stock solution:
 - Determine amount of PRAZI-MED to be added from the appropriate dosing chart below.
 - Add the measured amount of PRAZI-MED™ to a closed container of at least 2 liters of aquarium or pond water.
 - You may substitute aquarium or pond water with purified water.
 - Mix vigorously to dissolve. Visible particles in the solution will not affect its effectiveness.
- Slowly pour the stock solution into the aquarium or pond in an area of high water flow.
- Maintain aeration and water flow during treatment.
- Do not conduct water changes for 7 days.

Day 8

- Repeat treatment (steps 2-5).

Day 15 (Seven days after second treatment)

- Protein skimmer can be re-activated now.
- Replace chemical filtration and/or activated carbon in the aquarium or pond and wait 24 hours before conducting a 20% water change.
- See STORAGE, HANDLING AND DISPOSAL for additional details on how to manage treated water. Do not discharge directly into the environment.

During treatment, if abnormal behavior or adverse events are observed in the tank inhabitants, discontinue treatment, conduct a 20% water change, re-activate protein skimmer and add activated carbon and/or chemical filtration to the system.

DOSING INSTRUCTIONS

To determine the appropriate amount of PRAZI-MED™ to add to aquarium or pond, first calculate aquarium or pond size:

7.48 x (length (feet) x width (feet) x average depth (feet)) = _____ US gallons

Refer to the dosing chart that corresponds to your specific container size of PRAZI-MED™.

Refer to the dosing chart below that corresponds to your specific container size of PRAZI-MED™. It is important to use the correct dosing chart because the measuring scoops included in the packaging are different sizes. Only use the scoop included.

DOSING CHARTS

All dosing charts are calculated using a standard dose of 10.2 mg/gallon (2.7 mg/L) of PRAZI-MED™.

10 gram mylar packet of PRAZI-MED™:

Use the following dosing chart to treat water volumes equal to or less than 250 gallons.

Dosing chart for use with 10 gram mylar packet of PRAZI-MED™ and enclosed 250 mg scoop*

Water Volume (Gallons)	# of 250 mg Scoops of PRAZI-MED™
12.5	½
25	1
50	2
75	3
100	4
250	10

*Use the dosing chart as a reference and combine the appropriate number of scoops to treat your specific aquarium or pond water volume.

50 gram bottle of PRAZI-MED™:

Use the following dosing chart to treat water volumes equal to or greater than 250 gallons.

Dosing chart for use with 50 gram bottle of PRAZI-MED™ and enclosed 1 gram scoop*

Water Volume (Gallons)	# of 1 gram Scoops of PRAZI-MED™
250	2.5 scoops
500	5
750	7.5
1,000	10
2,500	25
5,000	Add one entire 50 gram bottle
10,000	Add two entire 50 gram bottles

*Use the dosing chart as a reference and combine the appropriate number of scoops to treat your specific aquarium or pond water volume.

250 gram bottle of PRAZI-MED™:

Using a gram scale, measure the appropriate amount of PRAZI-MED™ to treat water volumes equal to or greater than 250 gallons. *No scoop included. Dosing chart provides the dose in grams.

Dosing chart for use with 250 gram bottle of PRAZI-MED™

Water Volume (Gallons)	Grams of PRAZI-MED™
250	2.5 grams
500	5
750	7.5
1,000	10
2,500	25
5,000	50
7,500	75
10,000	100
25,000	Add one entire 250 g bottle

HOW SUPPLIED: 10 gram mylar packet in carton, 50 gram PET bottle, 250 gram PET bottle.

STORAGE, HANDLING AND DISPOSAL:

Store at or below 25°C and protect from light. Keep product and empty container away from heat and sources of ignition.

Do not conduct water changes during the treatment period. Prior to conducting a water change, subject treated water to protein skimming, chemical filtration and/or activated carbon for at least 24 hours prior to discharge to remove residual drug. Dispose of unused product, spills, and treated water in a manner that will not lead to contamination of surface water. Contact your State Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance pertaining to disposal of unused product.

QUESTIONS/COMMENTS?

To report side effects, for technical assistance or to request an SDS, contact AQION at 1-719-256-0044. For additional information about reporting side effects for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Manufactured for: Aqion LLC, 539 W. Commerce Street, Suite 6825, Dallas, TX 75208 U.S.A.

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Rev. 01/2026

NDC# 43457-534-25

USES: PRAZI-MED™ (praziquantel powder for immersion) is used for the treatment of internal parasites (flukes and tapeworms) and external parasites (flukes) susceptible to praziquantel in ornamental finfish, except *Callichthyidae* and *Clariidae* catfish. For accurate dosing, use the enclosed 1 gram scoop and refer to the dosing chart for use with the 50 gram bottle included in the package insert. Before using this drug, read package insert for full product information.

STORAGE, HANDLING, AND DISPOSAL: Store at or below 25°C (77°F) and protect from light. Keep product and empty container away from heat and sources of ignition.

Prazi-Med™ (praziquantel powder for immersion)

For use in ornamental finfish, except *Callichthyidae* and *Clariidae* catfish

For aquariums and ponds equal to or greater than 250 gallons.

1 gram Measuring Scoop included

Net Contents: 50 grams

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Lot

Before using this drug, read package insert located inside bottle for full product information. Refer to the dosing chart for use with the 250 gram bottle included in the package insert.

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STORAGE, HANDLING, AND DISPOSAL: Store at or below 25°C (77°F) and protect from light. Keep product and empty container away from heat and sources of ignition. See package insert for further instructions for disposing of treated water.

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**NET CONTENTS:
250 grams**

For aquariums and ponds equal to or greater than 250 gallons.



8 50050 4240

5"

1"

5"

1"



PRAZIMED
praziquantel powder

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:43457-643
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	1 g in 1 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43457-643-11	1 in 1 BOX		
1	NDC:43457-643-10	10 g in 1 POUCH		
2	NDC:43457-643-51	1 in 1 JAR		
2	NDC:43457-643-50	50 g in 1 POUCH		
3	NDC:43457-643-26	1 in 1 JAR		
3	NDC:43457-643-25	250 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
legally marketed unapproved new animal drugs for minor species	MIF900054	04/02/2026	

Labeler - KDG Impresa LLC, Aqion (036363181)**Registrant** - KDG Impresa LLC, Aqion (036363181)**Establishment**

Name	Address	ID/FEI	Business Operations
KDG Impresa LLC, Aqion		036363181	repack, relabel