

AQUACALM - metomidate powder
Western Chemical Inc.

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.

Aquacalm™ (Metomidate hydrochloride) For immersion use in ornamental finfish only. Not for use in fish intended for human or animal consumption. NOT APPROVED BY FDA – Legally marketed as an FDA indexed product under MIF 900-002. Extra-label use is prohibited. Note--In order to be legally marketed, an animal drug product intended for a minor species must be Approved, Conditionally Approved, or Indexed. THIS PRODUCT IS INDEXED. It is a violation of Federal law to use this product in a manner other than as directed in the labeling. As used on this label, the words "ornamental fish" refer to a wide variety of finfish species maintained primarily for their appearance and do not include any fish that are consumed by humans or food-producing animals.

NET CONTENTS: 1, 5, 10 or 50 grams

DESCRIPTION: Each gram of Aquacalm™ powder contains 1 gm of metomidate hydrochloride. Aquacalm™ acts on the central nervous system to induce sedation or anesthesia in fish immersed in water containing the drug.

INDICATION: For the sedation and anesthesia of ornamental finfish. Aquacalm™ is not for use in fish intended for human or animal consumption. Sedation may be necessary in situations such as strip spawning for hatchery rearing, transporting fish from supplier to wholesaler or retailer, photographing fish as part of a strategic marketing approach, or removal of fish from exhibit tanks prior to cleaning. Anesthesia may be necessary in situations where detailed fish examination or minor surgical procedures are to be conducted.

CAUTION:
FOR USE IN ORNAMANTAL FINFISH ONLY.
NOT FOR USE IN FISH INTENDED FOR HUMAN OR ANIMAL CONSUMPTION.

WARNING:

Not for use in humans. Keep out of the reach of children. Use in a well-ventilated area. Wear gloves.

INHALATION: May be harmful. Remove immediately from danger zone and provide fresh air. In case of respiratory problems or respiratory arrest, administer artificial respiration. Keep the affected individual warm and still. Contact emergency medical help.

INGESTION: May be harmful. If the person is conscious, wash out mouth with copious amounts of water. Contact emergency medical help.

EYE CONTACT: May be harmful. In case of contact, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Contact emergency medical help.

SKIN CONTACT: May be harmful. In case of contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and wash before re-using. Contact emergency medical help.

OTHER HEALTH INFORMATION: The toxicological properties of metomidate hydrochloride have not been thoroughly investigated. It is thought to act on the central nervous system as an imidazole based non-barbiturate hypnotic.

To obtain a Material Safety Data Sheet, call WESTERN CHEMICAL INC. at (360) 384-5898, or visit www.wchemical.com

DIRECTIONS FOR USE:

Aquacalm™ is packaged as a dry powder and must be mixed with water to be used. Determine the amount of Aquacalm™ powder needed to achieve the desired concentration for the intended use. Dissolve Aquacalm™ in a known volume of water, mix well, and aerate water during sedation or anesthesia. Lightly sedated fish may lose their ability to maintain upright position or position in a stream flow. Deeply sedated or anesthetized fish will experience total loss of equilibrium. Before beginning sedation or anesthesia, ensure that Aquacalm™-free water is available for recovery. Always test the dosage on a small group of fish first to make sure no unintended or adverse effects occur.

SPECIES:

Aquacalm™ has been tested on representative ornamental finfish species, but has not been tested on all fish species. The effect of Aquacalm™ may vary between (and within) species, depending upon age and physical condition of fish, and under different water conditions. Sedate or anesthetize fish in water with temperature and pH close to the temperature and pH of the rearing water.

Caution should be taken when using this product on/for:

1. Larval fish species, which may be more sensitive to sedation than older fish of the same species
2. Fish species such as knifefish and gouramis
3. Any fish species for extended periods (e.g. > 24 hr) used during transportation

DOSAGE:

Dose for sedation: 0.1 to 1.0 mg/L

Dose for anesthesia: 1.0 to 10.0 mg/L

The dose should be individualized, depending upon the fish species and the degree of anesthesia required. Consideration should be taken when sedating or anesthetizing fish at water temperatures substantially different from the species preferred water temperature or at very low pH.

DURATION OF TREATMENT:

At doses suitable for total loss of equilibrium or anesthesia, do not expose fish for more than 60 min. At doses suitable to sedate fish for transportation, do not expose fish for more than 24 hr. To facilitate recovery upon removal from a solution of Aquacalm™, place fish in well oxygenated, high quality water free of Aquacalm™. Fish should recover in 20 to 90 min.

CONTRAINDICATIONS:

Use of Aquacalm™ is contraindicated in species of fish that rely upon accessory air breathing organs for oxygen consumption. Sedation or anesthesia of such species may result in unacceptable rates of mortality.

DOSE CALCULATION:

The dose is based on the volume of water in which fish will be placed or held.

For example, if the desired Aquacalm™ concentration is 2.0 mg/L and the tank holding the fish contains 10 L of water, use the following calculation:

$$2 \text{ mg/L} \times 10 \text{ L} = 20 \text{ mg} = 0.02 \text{ g Aquacalm}^{\text{TM}}$$

For example, if the desired Aquacalm™ concentration is 2.0 mg/L and the tank holding the fish contains 5 gal of water, use the following calculation (note that the correction factor is used when volume is reported in gallons):

$$2 \text{ mg/L} \times 5 \text{ gal} \times 0.00378 = 0.038 \text{ g Aquacalm}^{\text{TM}}$$

STORAGE and HANDLING:

Store at 10°C to 30°C (50°F to 86°F) and protect from sunlight and sources of heat.

DISPOSAL:

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? For technical assistance, call Western Chemical Inc. at (360) 384-5898. To report an adverse event, call WESTERN CHEMICAL INC. at (360) 384-5898, or FDA at 1-888-FDA-VETS.

1 gram

Aquacalm™
(Metomidate hydrochloride)

For use in ornamental finfish only. Extra-label use is prohibited.
Before using, read package insert for complete product information.
NOT APPROVED BY FDA – Legally marketed as an FDA Indexed
Product under MIF 900-002. Store at 10°C to 30°C (50°F to 86°F).
NDC No.: 50378-013-01

Lot:

Exp:

WESTERN CHEMICAL INC.
1269 Lattimore Road, Ferndale WA 98248
www.wchemical.com

10 grams

Aquacalm™
(Metomidate hydrochloride)

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NDC No.: 50378-013-10

Lot:

Exp:

WESTERN CHEMICAL INC.
1269 Lattimore Road, Ferndale WA 98248
www.wchemical.com

5 grams

Aquacalm™
(Metomidate hydrochloride)

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Product under MIF 900-002. Store at 10°C to 30°C (50°F to 86°F).
NDC No.: 50378-013-05

Lot:

Exp:

WESTERN CHEMICAL INC.
1269 Lattimore Road, Ferndale WA 98248
www.wchemical.com



Western Chemical Inc
1269 Lattimore Road
Ferndale, WA 98248
(800)283-5292 or
(360)384-59-898

www.wchemical.com

1 Gram 5 Grams 10 Grams

NOT APPROVED BY FDA
Legally marketed as an
FDA Indexed Product
under MIF 900-002.
Extra-label use is
prohibited

Lot: _____

Exp: _____

NDC Number: 50378-013-01
50378-013-05
50378-013-10

AQUACALM™
(Metomidate hydrochloride)

Each gram contains 1,000 mg
metomidate hydrochloride

For use in ornamental finfish only.
Not for use in fish intended for
human or animal consumption.
See Package Insert



INDICATION:
Aquacalm™ is for the sedation
and anesthesia of ornamental
fish. It is not for use in fish
intended for human or animal
consumption.
Dose for
Sedation: 0.1 – 1.0 mg/L
Anesthesia: 1.0–10.0 mg/L
Directions: For complete
directions, see package insert.
Warnings: Not for use in humans.

**KEEP OUT OF REACH OF
CHILDREN.**

NOT APPROVED BY FDA
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Indexed Product under MIF
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50 grams

AQUACALM™
(Metomidate hydrochloride)

Each gram contains 1,000 mg
metomidate hydrochloride

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Not for use in fish intended for
human or animal consumption.
See Package Insert



INDICATION:
Aquacalm™ is for the sedation and
anesthesia of ornamental fish. It is not
for use in fish intended for human or
animal consumption.
Dose for
Sedation: 0.1 – 1.0 mg/L
Anesthesia: 1.0–10.0 mg/L
Directions: For complete directions,
see package insert.
Warnings: Not for use in humans.

KEEP OUT OF REACH OF CHILDREN.

Lot: _____

Exp: _____

NDC Number: 50378-013-50

AQUACALM

metomidate powder

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:50378-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
metomidate (UNII: Z18ZYL8Y51) (metomidate - UNII:Z18ZYL8Y51)	metomidate	1000 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50378-013-02	1 in 1 CARTON		
1	NDC:50378-013-01	1 g in 1 BOTTLE, PLASTIC		
2	NDC:50378-013-06	1 in 1 CARTON		
2	NDC:50378-013-05	5 g in 1 BOTTLE, PLASTIC		
3	NDC:50378-013-11	1 in 1 CARTON		
3	NDC:50378-013-10	10 g in 1 BOTTLE, PLASTIC		
4	NDC:50378-013-50	50 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Legally Marketed Unapproved New Animal Drugs for Minor Species	MIF900002	06/15/2009	

Labeler - Western Chemical Inc. (085803500)**Registrant** - Western Chemical Inc. (085803500)

Revised: 9/2012

Western Chemical Inc.