

MEDIAQUA PREMIUM- hypochlorous acid liquid
Mediecotech co ltd

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.

Drug Facts

Hypochlorous Acid

WATER, sodium chloride

sterilization, disinfection

KEEP OUT OF REACH OF THE CHILDREN

Apply an appropriate amount on your hands and rub well to dry.

1. Do not use on the following body parts. A wide range of body parts and damaged skin around the eyes and ears, in the oral cavity (may have irritating effects)
2. If the following symptoms appear, stop using them immediately and consult a doctor or pharmacist.
 - 1) Hypersensitivity symptoms such as rash, erythema, itching, and edema
 - 2) Skin irritation symptoms

for external use only

Mediaqua premium

<i>Drug Facts</i>	
<i>Active Ingredients</i> <u>Hypochlorous acid</u>	<i>Purpose</i> Disinfecting Agent
<i>Uses</i> ■ sterilization, disinfection	
<i>Warning</i> For external use only When using this product ■ if following abnormal symptoms persist, discontinue use Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes ■ Stop immediately and consult a doctor if you experience <ol style="list-style-type: none">1) Hypersensitivity symptoms such as <u>erythema</u>, itching and dermatitis.2) Skin Irritation3) Following Instructions when using medication<ol style="list-style-type: none">(1) For external use only (Do not use internally)(2) Avoid getting into the eyes (if contact occurs, wash well with	

clean water)

■ Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.

■ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin.

It is not recommended to use this one areas that have been medically treated with a cast or bandage.

■ Do not use in combination with soap or antibacterial cleansing agents.

Directions

■ take appropriate amount where needed

Other Information

- read the directions and warnings before use

- avoid freezing and excessive heat above 40 degree C (104 degree F)

Inactive Ingredients

Water, sodium chloride

MEDIAQUA PREMIUM

hypochlorous acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80458-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYPOCHLOROUS ACID (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	0.01 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80458-0001-1	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/03/2020	

Labeler - Mediecotech co ltd (694790898)

Registrant - Mediecotech co ltd (694790898)

Establishment

Name	Address	ID/FEI	Business Operations
Mediecotech co ltd		694790898	manufacture(80458-0001)

Revised: 9/2020

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