

HYDROGEN PEROXIDE- hydrogen peroxide solution
Cariba International

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Hydrogen Peroxide 3%
871.001/871AA

Active ingredient

Hydrogen peroxide (stabilized) 3%

Purpose

First Aid Antiseptic

Oral debriding agent

Uses

- first aid to help prevent the risk of infection in minor cuts, scrapes and burns
- aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth

Warnings

For external use only

Do Not Use

- in the eyes or apply over large areas of the body
- longer than 1 week

Ask a doctor before use if you have

deep or puncture wounds, animal bites or serious burns

Stop Use and ask a doctor if

- the condition persists or gets worse
- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

First Aid antiseptic:

- clean the affected area
- apply a small amount of product on the affected area 1 to 3 times a day
- may be covered with a sterile bandage
- if bandaged, let dry first

Oral debriding agent (oral rinse): adults, children over 2 years of age:

- mix with an equal amount of water
- swish around in the mouth over the affected area for at least 1 minute, then spit out
- use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor
- children under 12 years of age should be supervised in the use
- children under 2 years of age: consult a dentist, doctor

Other information

Keep tightly closed and at controlled room temperature. Do not shake bottle. Hold away from face when opening.

Inactive ingredients

purified water

Distributed by: Cariba International

P.O. Box 1208

Safety Harbor, Florida 34695

MADE IN USA WITH US AND FOREIGN COMPONENTS

principal display panel

Do not use if printed seal under cap is broken or missing

CARIBA CARE

HYDROGEN PEROXIDE

TOPICAL SOLUTION USP

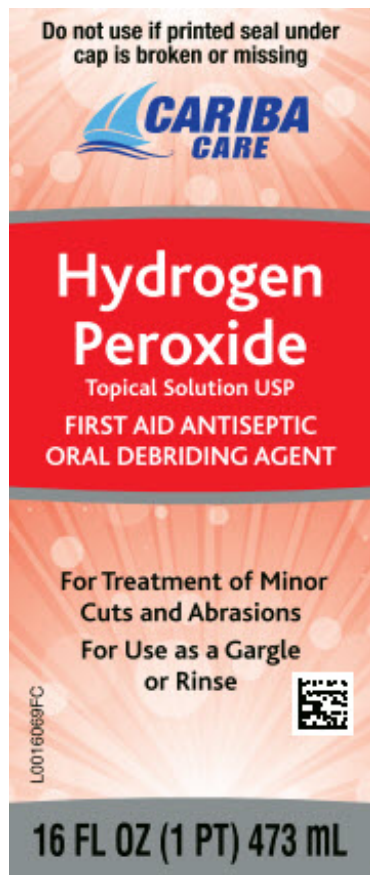
FIRST AID ANTISEPTIC

ORAL DEBRIDING AGENT

For Treatment of Minor Cuts and Abrasions

For Use as a Gargle or Rinse

16 FL OZ (1 PT) 473 mL



HYDROGEN PEROXIDE

hydrogen peroxide solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67860-871
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:67860-871-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/28/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		10/28/2016	

Labeler - Cariba International (049354067)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(67860-871)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(67860-871)