HYDROGEN PEROXIDE- hydrogen peroxide liquid Dyad Medical Sourcing, LLC

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

Drug Facts

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, mucous, 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 area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

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

- mix with an equal amount of water
- swish around in the mouth over the affected area for at least 1 minute and 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 of this product
- children under 2 years of age: consult a dentist or doctor

Other information

Keep tightly closed in a cool dark place. Do not shake bottle. Hold away from face when opening.

Inactive ingredient

purified water

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

HCS

NDC 53175-001-16

Solution of Hydrogen Peroxide 3% USP 10 Volume 3% FIRST AID ANTISEPTIC 16 fl. oz. (473 mL)

Manufactured for:

Dyad Medical Sourcing, LLC 2101 Waukegan Road, Suite 208 Bannockburn, IL 60015

Made in USA

#902-HCS0202 Rev. 01 ©2012 Dyad Medical Sourcing, LLC

1-855-241-1773 • info@dyadms.com



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Inactive ingredient purified water

1-07-D0012D14 Rev.0

Item No. HCS0202

HYDROGEN PEROXIDE

hydrogen peroxide liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53175-001

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

Hydrogen Peroxide (UNII: BBX060AN9V) (Hydrogen Peroxide - UNII:BBX060AN9V)

Hydrogen Peroxide

 $3\ mL$ in $100\ mL$

Inactive Ingredients

Ingredient Name

Strength

Water (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53175-001-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2012	
2	NDC:53175-001-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2012	
3	NDC:53175-001-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2012	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC MONOGRAPH NOT FINAL	part356	09/10/2012				

Labeler - Dyad Medical Sourcing, LLC (078572603)

Revised: 12/2019 Dyad Medical Sourcing, LLC