HYDROGEN PEROXIDE- hydrogen peroxide liquid TOP CARE (Topco Associates 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.

Drug Facts

Active ingredient

Hydrogen peroxide 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 one week

Ask a doctor before use if you have

• deep puncture wounds, animal bites or serious burns

Stop use and ask a docotr 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 (1-800-222-1222) right away.

Directions

For use as a first aid antiseptic:

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

For use as an 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 affected area for at least 1 minute and then spit out. Do not swallow.
- use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor
- **children under 12 years** should be supervised in the use of this product
- **children under 2 years of age**: consult a doctor or dentist

Other information

- keep tightly closed and in a dark place at room temperature
- do not shake bottle. Hold away from face when opening.

Inactive ingredient

purified water

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

3% USP Hydrogen Peroxide

FIRST AID ANTISEPTIC/ORAL DEBRIDING AGENT

- For treatment of minor cuts, scrapes and burns
- For use as an antiseptic gargle or rinse

FL OZ (mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

www.topcarebrand.com

Package Label



3% USP Hydrogen Peroxide

FIRST AID ANTISEPTIC/ ORAL DEBRIDING AGENT

- For Treatment of Minor **Cuts, Scrapes & Burns**
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32 FL OZ (1 QT) 946 mL

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Inactive ingredient purified water

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Visit here for more information: http://topbrnds.com/48zr84

PLD-C220C LB005210



TOPCARE HEALTH 3% USP Hydrogen Peroxide

HYDROGEN PEROXIDE

hydrogen peroxide liquid

Product Information

HUMAN OTC DRUG NDC:36800-214 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V) (HYDRO GEN PERO XIDE - UNII: BBX060AN9V)	HYDROGEN PEROXIDE	2.65 mL in 100 mL		

Inactive Ingredients					
Ingredient Name	Strength				
WATER (UNII: 059QF0KO0R)					

]	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-214- 16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2009		
2	NDC:36800-214- 32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2009		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part356	05/15/2009		

Labeler - TOP CARE (Topco Associates LLC) (006935977)

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