DOP HYDROGEN PEROXIDE 3% - hydrogen peroxide liquid Omega & Delta Co. Inc.

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.

DOP Hydrogen Peroxide 3% Topical Solution USP

Drug Facts

Active Ingredient

Hydrogen peroxide 3% (stabilized)

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

IKeep 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 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 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 a doctor

Other Information

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

Inactive Ingredient

Purified Water

Distributed by:

□Omega & Delta Co., Inc.

Garolina, P.R. 00984

Principal Display Panel

DOP

HYDROGEN

PEROXIDE

(AGUA OXIGENADA)

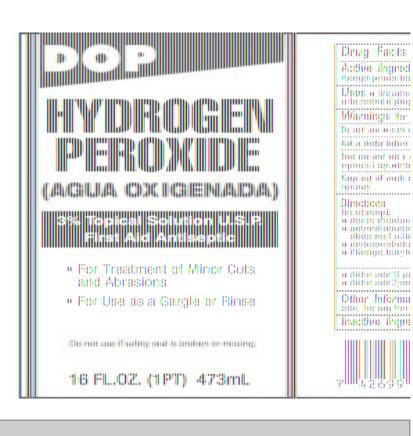
3% Topical Solution U.S.P.

First Aid Antiseptic

- For Treatment of Minor Cuts and Abrasions
- For Use as a Gargle or Rinse

Do not use if safety seal is broken or missing.

16 FL.OZ. (1PT) 473 mL



DOP HYDROGEN PEROXIDE 3%

hydrogen peroxide liquid

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:51048-040

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

HYDROGEN PERO XIDE (UNII: BBX060 AN9 V) (HYDROGEN PERO XIDE UNII:BBX060 AN9 V)

HYDROGEN
PERO XIDE

3 g
in 100 mL

Inactive Ingredients

Ingredient Name Strength
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51048-040- 16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 0	
	NDC:51048-040- 08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 6	
3	NDC:51048-040- 32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 10	

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph not final	part333A	0 1/0 1/20 0 0						

Labeler - Omega & Delta Co. Inc. (090317793)

Establishment									
Name	Address	ID/FEI	Business Operations						
Omega & Delta Co. Inc.		090317793	manufacture(51048-040)						

Revised: 11/2020 Omega & Delta Co. Inc.