

HYDROGEN PEROXIDE- hydrogen peroxide solution

Hydrox Laboratories

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.

SOLUTION OF HYDROGEN PEROXIDE 3% USP 10 VOLUME

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

**OPTIMATES
HYDROX
CHEMICALS
TRADEMARK
SINCE 1913**

Hydrox

NDC 10565-001-16

**SOLUTION OF
HYDROGEN PEROXIDE
3% USP 10 VOLUME**

3%

TAMPER EVIDENT CAP FOR YOUR PROTECTION.

IF RING-BAND IS DETACHED FROM CAP OR MISSING DO NOT USE.

FIRST AID ANTISEPTIC

Made in USA

16 FL. OZ. (473 mL)



HYDROGEN PEROXIDE

hydrogen peroxide solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10565-001
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:10565-001-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/1993	
2	NDC:10565-001-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/1993	
3	NDC:10565-001-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/1993	
4	NDC:10565-001-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/1993	
5	NDC:10565-001-99	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/1993	

Labeler - Hydrox Laboratories (025164302)

Registrant - Hydrox Laboratories (025164302)

Establishment

Name	Address	ID/FEI	Business Operations
Hydrox Laboratories		025164302	MANUFACTURE(10565-001) , label(10565-001) , pack(10565-001)

