

HYDROGEN PEROXIDE - hydrogen peroxide solution
Worldwide Sales & Distribution Corp.

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.

Quality Guaranteed Hydrogen Peroxide Solution

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
- aid 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
- more than one week

Consult a doctor before use if you have animal bites or serious burns, deep or punctured wounds

Stop use and ask a doctor if

- the condition persists or gets worse
- sore mouth symptoms do not improve in a week
- pain redness or irritation persists or if you develop fever, rash or swelling

Keep out of reach of children

If swallowed seek professional assistance or contact a poison control center immediately

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
- let dry first before using bandage

Oral debriding agent (oral rinse)

Adults and children 2 years of age and over:

- mix with 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 doctor or dentist

- children under 2 years of age: consult a dentist or doctor
- children under 12 years of age should be supervised in the use of this product

Other information

Keep tightly closed in a dark place at controlled room temperature

Do not shake bottle. Keep away from face when opening

Inactive ingredient

Purified water

Package Label

Quality Guaranteed

Hydrogen Peroxide Solution

U.S.P

First Aid Antiseptic Oral Debriding Agent

TEMPER EVIDENT : Do not use if printed safety seal on cap is broken or missing

16 FL OZ (1 PT) 473ml

Drugs Facts	
Active Ingredients Hydrogen peroxide 3%.....	Purpose First aid antiseptic/oral debriding agent
Uses • first aid to help prevent risk of infection in minor cuts, scrapes and burns • aid in the removal of phlegm, mucus or other secretion associated with occasional sore mouth	
Warning For external use only	
Do not use • in the eyes or apply over large areas of the body • more than one week	
Consult a doctor before use if you have animals bites or serious burns, deep or punctured wounds	
Stop use and consult a doctor if • the condition persists or gets worse • sore mouth symptoms do not improve in a week • pain redness or irritation persists or if you develop fever, rash or swelling	
Keep out of reach of children If swallowed seek professional assistance or contact a poison control center immediately	
Directions First aid antiseptic • clean affected area	oral debriding agent (oral rinse) <i>Adults and children 2 years and over</i>
• apply a small amount on the affected area 1-3 times a day	• mix with an equal amount of water
• may be covered with a sterile bandage	• swish around in the mouth over affected area for at least 1 minute then spit out
• let dry first before using bandage	• use up to 4 times daily after meals and at bedtime or as suggested by a doctor or dentist
for children under 2 years : consult a dentist or a doctor children under 12 years should be supervised in the use of this product	
Other information Keep tightly closed in a dark place at a controlled room temperature Do not shake the bottle. Keep away from face when opening	
Inactive ingredients Purified water	Imported by : w.w.s. Bayonne NJ 07002 Neutral Code : COS/GUJ/GC-670 B.No. 95 Mfg Dt. 09/2010 Exp.Dt.08/2013
MADE IN INDIA	

HYDROGEN PEROXIDE			
hydrogen peroxide solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76384-007
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 kg in 100 L
Inactive Ingredients			
	Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76384-007-01	.473 L in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/25/2011	

Labeler - Worldwide Sales & Distribution Corp. (627014330)**Establishment**

Name	Address	ID/FEI	Business Operations
Stellar Mercantile Pvt. Ltd.		650493005	manufacture

Revised: 8/2011

Worldwide Sales & Distribution Corp.