COMFORT- hydrogen peroxide liquid Weimei Lianyungang Household Articles manufacturing, Co. LTD

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.

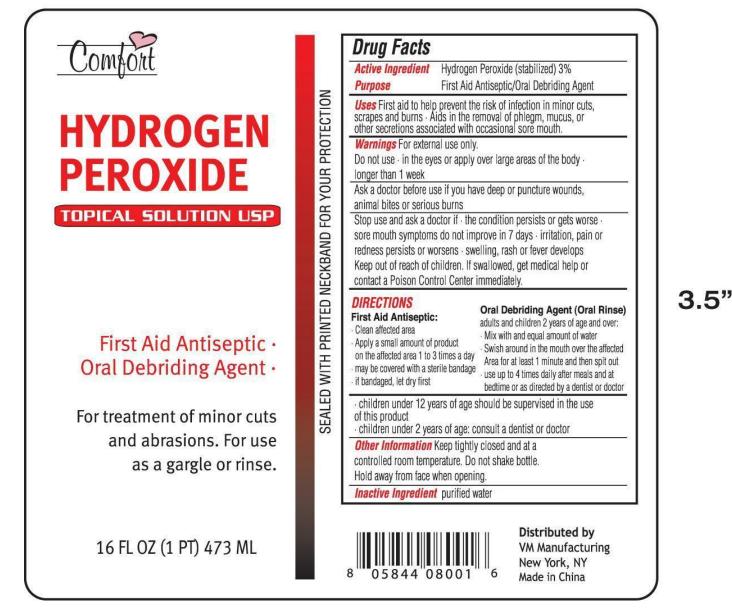
Active Ingredient

Hydrogen Peroxide (Stablized) 3%

Package Label

Hydrogen Peroxide

3.75"



Purpose

First Aid Antiseptics/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 secrections assocated 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 a week

Ask a doctor bbefore use if you have deep or punture wounds, animal bits 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.

Irriation, pain or redness persists or worsens. swelling, rash, or fever develops. Keep reach out of children. If swallowed, get medical help or contact a poison control center immediately.

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Directions

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 bandage, 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 affected area for atleast 1 minute and spit out use up to 4x 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 dentist or doctor

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Other Information

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

Inactive Ingredient

Purified water

COMFORT								
	1							
hydrogen peroxide liqui	a							
Product Information	1							
Product Type		HUMAN OTC DRUG	Item Co	Item Code (Source)		NDC:5	NDC:50827-650	
Route of Administration	ı	TOPICAL						
Active Ingredient/A		•						
Ingredient Name					Basis of Strength		Strength	
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXI UNII:BBX060AN9V)				HYDRO GEN PERO XIDE			2.65 mL in 100 mL	
Inactive Ingredients	;							
Ingredient Name					Strength			
WATER (UNII: 059QF0KO	0 R)							
Packaging								
# Item Code	Pa	ckage Description	Market	Marketing Start Date		Marketing End Date		
1 NDC:50827-650-16	473 mL in 2	BOTTLE, PLASTIC						
Marketing Inform	mation							
Marketing Category	Applicat	ion Number or Monograp	h Citation	Market	ing Start I	Date Mar	keting End Date	
OTC monograph not final	part333A			06/01/20	12			

Labeler - Weimei Lianyungang Household Articles manufacturing, Co. LTD (546100731)

Registrant - Weimei Lianyungang Household Articles manufacturing, Co. LTD (546100731)

Establishment								
Name	Address	ID/FEI	Business Operations					
Weimei Lianyungang Household Articles manufacturing, Co. LTD		546100731	manufacture(50827-650)					

Revised: 5/2012

Weimei Lianyungang Household Articles manufacturing, Co. LTD