

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"

Comfort

HYDROGEN PEROXIDE

TOPICAL SOLUTION USP

**First Aid Antiseptic ·
Oral Debriding Agent ·**

For treatment of minor cuts
and abrasions. For use
as a gargle or rinse.

16 FL OZ (1 PT) 473 ML

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

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, 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

First Aid Antiseptic:

- Clean 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
- if bandaged, let dry first

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

Inactive Ingredient purified water

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Distributed by
VM Manufacturing
New York, NY
Made in China

3.5"

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 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 a 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 reach out of children. If swallowed, get medical help or contact a poison control center immediately.

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Directions

first aid antiseptic:

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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

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children under 12 years should be supervised in the use of this product

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children under 12 years 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 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				
hydrogen peroxide liquid				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50827-650	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)		HYDROGEN PEROXIDE	2.65 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50827-650-16	473 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/01/2012		

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