BERKLEY JENSEN ANTISEPTIC- hydrogen peroxide liquid TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI

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.

Berkley Jensen 3% Hydrogen Peroxide

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. *Aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth.

Warnings

For external use only.

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns.

Stop use and ask a doctor if *swelling, rash, or fever develops. *the condition persists or gets worse. *sore mouth symptoms do not improve in 7 days. *irritation, pain or redness persists or worsens.

Keep out of reach of children. If swallowed, get medical help or contact poison control center right away.

stop use

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Ask doctor

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns.

Do not use

Do not use *in the eyes or apply over large areas of the body. *longer than one week.

Directions For use as a first aid antiseptic:

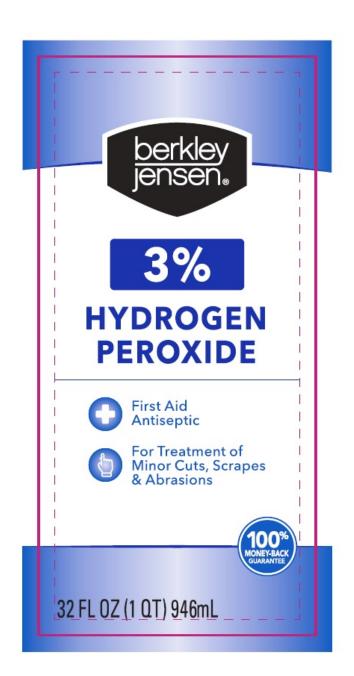
- Clean affected area.
- apply small amount of product on affected area 1-3 times a day.
- may be covered with a sterile bandage.
- For use as an oral debriding agent (oral rinse):
- adults and children 2 years of age and over
- mix with an equal amount of water.
- swish around in the mouth over affected area for at least 1 minute and then spit out. Do not swallow.
- use up to 4 times 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.

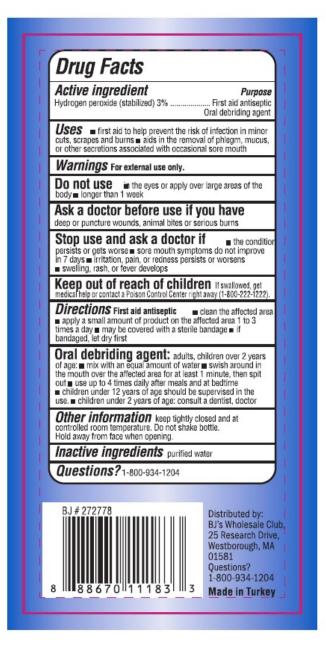
Other information

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

Inactive ingredient purified water

Packaging





BERKLEY JENSEN ANTISEPTIC

hydrogen peroxide liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76772-028

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	HYDROGEN PEROXIDE	30 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76772- 028-95	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/23/2021		

Labeler - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Registrant - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Establishment				
Name	Address	ID/FEI	Business Operations	
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI		533120570	manufacture(76772-028)	

Revised: 6/2021 TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI