

LUXURY 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.

Luxury 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

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.

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

LUXURY Hydrogen Peroxide 3%

→ First Aid Antiseptic/
Oral Debriding Agent

→ For Treatment of Minor
Cuts & Abrasions

→ For Use as Gargle or Rinse

□ Square bottle uses less plastic
than a similarly sized round bottle
Recyclable (if available in your area)

Do not use if printed seal under
cap is broken or missing

DISTRIBUTED BY: TSM Brands LLC
540 Equinox Ln Manalapan, NJ 07726
www.tsmbrands.com

ITEM#6574

LUXURY
**Hydrogen
Peroxide 3%**
Topical Solution USP
SOLUTION
NATURAL

6 FL. OZ. (177 ML)

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 right away.	
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 ■ if bandaged, let dry first	
Oral debriding agent: adults, children over 2 years of age: ■ mix with an equal amount of water ■ swish around in the mouth over the affected area for at least 1 minute, then spit out ■ use up to 4 times daily after meals and at bedtime ■ children under 12 years of age should be supervised in the use. ■ children under 2 years of age: consult a dentist, doctor	
Other information keep tightly closed and at controlled room temperature. Do not shake bottle. Hold away from face when opening.	
Inactive ingredient purified water	

LUXURY ANTISEPTIC

hydrogen peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76772-023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	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
1	NDC:76772-023-17	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/10/2021	

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(76772-023)

Revised: 3/2021

TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI