

3% HYDROGEN PEROXIDE- hydrogen peroxide liquid
MBS Medical Technologies, Inc.

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.

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.

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

Directions For use as a first aid antiseptic: *Clean affected area. *if bandaged, let dry first. *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

Antiseptic


* For treatment of minor cuts and abrasions.

* Oral debriding agent.

* Use as a gargle or rinse.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Packaging



SimpliSterile™

3% HYDROGEN PEROXIDE

USP

ANTISEPTIC

- For treatment of minor cuts and abrasions
- Oral debriding agent
- Use as a gargle or rinse

16 FL OZ (1 PT) 473mL

Drug Facts

Active Ingredient	Purpose
Hydrogen peroxide 3%.....	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 one week	
Ask a doctor before use if you have ■ deep 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 (1-800-222-1222) immediately.	
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 bandaged, 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 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
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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	
Questions or comments? Call 1-888-482-4201 Monday-Friday 9AM-5PM PST	

Manufactured by:

MBS Medical Technologies, Inc.
 6750 N. Desert Blvd.
 El Paso, TX 79912
 mbsmedtech.com

MADE IN THE USA

UPC
CODE

3% HYDROGEN PEROXIDE

hydrogen peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79590-001
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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:79590-001-00	475 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/15/2020	

Labeler - MBS Medical Technologies, Inc. (117581535)

Registrant - MBS Medical Technologies, Inc. (117581535)

Establishment

Name	Address	ID/FEI	Business Operations
MBS Medical Technologies Inc		117581535	manufacture(79590-001)

Revised: 9/2020

MBS Medical Technologies, Inc.