

**HYDROGEN PEROXIDE- hydrogen peroxide liquid**  
**Universal Distribution Center LLC**

*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.*

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***Hydrogen peroxide Topical Solution USP 3%***

***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 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) right away.

***Directions For use 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
- if bandage, let dry first

***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 doctor or dentist

***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

***Topical Solution USP 3%***

**First Aid Antiseptic/Oral Debriding Agent**

For Treatment of Minor Cuts & Abrasions

For Use As a Gargle or Rinse

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

Distributed by:

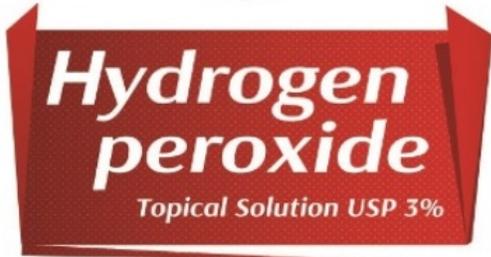
Universal Distribution Center

96 Distribution Boulevard

Edison, NJ 08817

Made in India

**Packaging**



**First Aid Antiseptic/  
Oral Debriding Agent**

**3%**

For Treatment of Minor  
Cuts & Abrasions

For Use As a Gargle or Rinse

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**16 FL OZ (1 PT) 473 mL**

<b>Drug Facts</b>	
<b>Active ingredient</b> Hydrogen peroxide 3%.....	<b>Purpose</b> First aid antiseptic/oral debriding agent
<b>Uses</b> • 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	
<b>Warnings</b> For external use only. <b>Do not use</b> • in the eyes or apply over large areas of the body • longer than one week <b>Ask a doctor before use if you have</b> • deep puncture wounds, animal bites or serious burns	
<b>Stop use and ask a doctor if</b> • 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	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
<b>Directions</b> 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 • if bandage, let dry first	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 doctor or dentist
<b>Other information</b> Keep tightly closed and in a dark place at room temperature Do not shake bottle. Hold away from face when opening.	
<b>Inactive ingredient</b> purified water	

MH/DRUGS/KD-313

Distributed by:  
Universal Distribution Center  
96 Distribution Boulevard  
Edison, NJ 08817



## HYDROGEN PEROXIDE

hydrogen peroxide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52000-025
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	3 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-025-40	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
2	NDC:52000-025-	119 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	11/25/2015	

41	Product	11/25/2015	
3	NDC:52000-025-42 178 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
4	NDC:52000-025-43 200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
5	NDC:52000-025-03 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
6	NDC:52000-025-44 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
7	NDC:52000-025-45 266 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
8	NDC:52000-025-31 295 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
9	NDC:52000-025-32 354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
10	NDC:52000-025-06 414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	
11	NDC:52000-025-07 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/25/2015	

**Labeler** - Universal Distribution Center LLC (019180459)

### Establishment

Name	Address	ID/FEI	Business Operations
BIOTEK INDIA		675484458	manufacture(52000-025)

Revised: 10/2020

Universal Distribution Center LLC