

**HYDROGEN PEROXIDE- hydrogen peroxide liquid**  
**Home Smart Products**

*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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**HEALTH SMART HYDROGEN PEROXIDE**

**Active ingredient (by volume)**

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
- on deep or puncture wounds, animal bites or on serious burns

**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
- swelling, rash or fever develops
- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens

**Keep this and all drugs out of reach of children.**

If swallowed, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

***first aid antiseptic:***

- clean the affected area
- apply small amount of product on the affected area 1-3 times a day
- may be covered with a sterile bandage
- if bandaged, let dry first

***oral debriding agent:***

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

**Inactive ingredients**

Water

**PRINCIPAL DISPLAY PANEL**

HEALTH SMART HYDROGEN PEROXIDE LIQUID  
FIRST AID ANTISEPTIC/ORAL DEBRIDING AGENT

16 FL.OZ (473 mL)

**HEALTH SMART™**

**HYDROGEN PEROXIDE SOLUTION U.S.P.**

**FIRST AID ANTISEPTIC**  
Do not use if safety seal on cap is broken or missing

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

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Drug Facts	
<b>Active Ingredients (by volume)</b>	<b>Purpose</b>
Hydrogen Peroxide 3%	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 - on deep or puncture wounds, animal bites or on serious burns	
<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 - swelling, rash or fever develops - sore mouth symptoms do not improve in 7 days - irritation, pain or redness persists or worsens	
<b>Keep this and all drugs out of reach of children.</b> If swallowed, seek professional assistance or contact a Poison Control Center immediately.	
<b>Directions</b>	
<b>first aid antiseptic:</b>	<b>oral debriding agent (oral rinse):</b>
<ul style="list-style-type: none"> <li>• clean affected area</li> <li>• apply small amount of product on affected area 1-3 times a day</li> <li>• may be covered with a sterile bandage</li> <li>• if bandaged, let dry first</li> </ul>	<ul style="list-style-type: none"> <li>• adults and children 2 years of age and over:</li> <li>• mix with an equal amount of water</li> <li>• swish around in the mouth over affected area for at least 1 minute and then spit out</li> <li>• use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor</li> </ul>
<ul style="list-style-type: none"> <li>• children under 12 years of age should be supervised in the use of this product</li> <li>• children under 2 years of age; consult a dentist or doctor</li> </ul>	
<b>Other Information</b> - Keep bottle tightly closed and in a dark place at a controlled room temperature. - Do not shake bottle - Hold away from face when opening	
<b>Inactive Ingredients:</b> Water	

MH-DRUGS/KD-313

MADE IN INDIA • DISTRIBUTED BY:  
HOME SMART PRODUCTS • SOUTHFIELD, MI

HS-01004

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**HYDROGEN PEROXIDE**

hydrogen peroxide liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52862-007
<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:52862-007-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
2	NDC:52862-007-03	119 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
3	NDC:52862-007-04	178 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
4	NDC:52862-007-05	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
5	NDC:52862-007-06	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
6	NDC:52862-007-07	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
7	NDC:52862-007-08	266 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
8	NDC:52862-007-09	295 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
9	NDC:52862-007-10	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
10	NDC:52862-007-11	414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	
11	NDC:52862-007-12	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2012	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/08/2012	

**Labeler** - Home Smart Products (161872676)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52862-007)