

BENEMAX ADVANCED HAND SANITIZER- hydrogen peroxide liquid

Nugale Pharmaceutical 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.

Drug Facts

Active ingredient

Hydrogen peroxide 3%

Purpose

Antiseptic

Warnings

For external use only. Do not use: In the eyes over large areas of the body, or for longer than 1 week. **Ask a doctor before use if you have** deep puncture wounds, animal bites or serious burns.

Stop use immediately and consult your physician if: The condition persists or worsens after use. If sore mouth symptoms do not improve in 7 days, If irritation, pain or redness persist or worsen. If swelling, rash or fever develop.

Uses

First aid to help prevent the risk of infection in minor cuts, scrapes and burns. Aids in the removal of phlegm, mucous or other secretions associated with occasional sore mouth.

Directions

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

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Inactive ingredient

Water

Other information

Keep tightly closed in a cool dark place • Do not shake bottle • Hold away from face when opening.

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.

Product label

  3% HYDROGEN PEROXIDE TOPICAL SOLUTION FIRST AID ANTISEPTIC/ ORAL DEBRIDING AGENT For treatment of minor cuts & abrasions Use as a gargle or rinse 16oz (473mL) NDC LOW OXIDATION FORMULA WITH NEW OPAQUE BOTTLE	DRUG FACTS	
	Active ingredient[s] Hydrogen Peroxide 3%First Aid Antiseptic/Oral Debriding Agent	Purpose
	Use[s] 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 <ul style="list-style-type: none">• in the eyes or over large areas of the body.• longer than one week.	
	When using this product keep out of eyes and ears. In case of contact with eyes, rinse eyes thoroughly with water.	
	Stop use and ask a doctor if: Irritation or rash occurs. The condition persist 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 a Poison Control Center right away at 1-800-222-1222.	
	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. If bandaged, let dry first.	
	Other information <ul style="list-style-type: none">• Keep tightly closed and in a dark place at room temperature.• Do not shake bottle, hold away from face when opening.	
	Inactive ingredients purified water	
For use as an oral debriding agent (oral rinse): Adults and children 2 years of age and over: <ul style="list-style-type: none">- 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.		
Distributed by: Prime Nutrisource Inc. 182 Whitman Ave, Edison NJ, 08817 1-866-795-7275 www.primenutrisource.com		

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BENEMAX ADVANCED HAND SANITIZER

hydrogen peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73700-003
Route of Administration	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:73700-003-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/25/2021	

Labeler - Nugale Pharmaceutical Inc (202595872)

Establishment

Name	Address	ID/FEI	Business Operations
Nugale Pharmaceutical Inc		202595872	manufacture(73700-003)

Revised: 3/2021

Nugale Pharmaceutical Inc