HYDROGEN PEROXIDE- hydrogen peroxide solution C.D.M.A.

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.

Hydrogen Peroxide 871.001/871AA

Active ingredient

Hydrogen peroxide (stabilized) 3%

Purpose

First aid antiseptic
Oral debriding agent

Uses

- first aid to help prevent the rise 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 then 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 (oral rinse): adults and children 2 years of age and over:

- mix with an 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

Children under 2 years of age: consult a dentist or 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

Distributed by C D M A., Inc

43157 W 9 Mile Rd, Novi, MI 48375

www.qualitychoice.com Questions: 800-935-2362

principal display panel

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

QC

QUALITY

CHOICE

Hydrogen

Peroxide

Topical

Solution

First Aid Antiseptic/

Oral Debriding Agent

For Treatment of Minor

Cuts and Abrasions

For Use as a Gargle or Rinse

32 FL OZ (946 mL)

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



Hydrogen Peroxide Topical Solution

First Aid Antiseptic/ Oral Debriding Agent

For Treatment of Minor Cuts and Abrasions

For Use as a Gargle or Rinse



32 FL OZ (946 ML)

L0018916FB

hydrogen peroxide solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63868-147

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active Molety				
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:63868- 147-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/1993	
2	NDC:63868- 147-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/11/1993	

Labeler - C.D.M.A. (011920774)

Registrant - Vi Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(63868-147)

Establishment	Esta	blis	hm	ent
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Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(63868-147)

Revised: 2/2023 C.D.M.A.