

HYDROGEN PEROXIDE- hydrogen peroxide solution

Vi-Jon

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 Mountain Falls

871

Active ingredient

Hydrogen peroxide (stabilized) 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 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

- 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

For First aid:

- clean the affected area
- spray 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: adults, children over 2 years of age:

- mix with an equal amount of water
- swish around in the mouth over the affected area for at least 1 minute, then spit out
- use up to 4 times daily after meals and at bedtime
- children under 12 years of age should be supervised in the use
- children 2 years of age: consult a dentist, doctor

Other information

keep tightly closed and at controlled room temperature. Do not shake bottle. Hold away from face when opening.

Inactive ingredients

purified water

Manufactured by: Vi-Jon, Inc., St. Louis, MO 63114

Questions or Comments? 1-888-593-0593

871.000/871AA

Alternate PDP for Swan Brand

Swan Hydrogen Peroxide Topical Solution USP

First Aid Antiseptic/Oral Debriding Agent

For treatment of minor cuts & abrasions

For use as a gargle or rinse

Square bottle uses less plastic than a similarly sized round bottle. Recyclable (if available in your area)

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

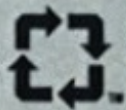
16 FL OZ (1 PT) 473 mL



HYDROGEN PEROXIDE

Topical Solution USP

- ▶ First Aid Antiseptic/
Oral Debriding Agent
- ▶ For Treatment of Minor
Cuts & Abrasions
- ▶ For Use As a Gargle or Rinse



Square bottle uses less plastic
than a similarly sized round bottle
Recyclable (if available in your area)

SEALED WITH PRINTED NECKBAND
FOR YOUR PROTECTION



16 FL OZ (1 PT) 473 mL

L0003648FA

principal display panel

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

for treatment of minor cuts and abrasions

3% U.S.P. hydrogen peroxide topical solution USP


first aid antiseptic

oral debriding agent

Made in the USA with US and foreign parts

32 FL OZ (1 QT) 946 mL

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




3% U.S.P.

for treatment of minor cuts and abrasions

hydrogen peroxide
topical solution USP
first aid antiseptic
oral debriding agent

L0016720FA



32 FL OZ (1 QT) 946 mL

HYDROGEN PEROXIDE

hydrogen peroxide solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0869-0871

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:0869-0871-72	295 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2017	
2	NDC:0869-0871-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2017	
3	NDC:0869-0871-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2017	
4	NDC:0869-0871-18	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2017	
5	NDC:0869-0871-99	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/09/2017	

Labeler - Vi-Jon (790752542)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(0869-0871)