

HYDROGEN PEROXIDE- hydrogen peroxide spray

Provision Medical

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 ingredients

Hydrogen Peroxide 3.0%

Purpose

First Aid Antiseptic

Uses

First aid to help prevent infection in minor cuts, scrapes and burns

Warnings

For external use only.

Do not use

- near eyes or mucous membranes
- on deep or puncture wounds, animal bites, or serious burns consult a physician

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Caution

- not for use on large areas of the body
- if redness, irritation, swelling or pain persists or increases, discontinue use and consult a physician

Directions

- spray over cleaned affected area 1 to 3 times daily
- if bandaged, let dry first

Inactive ingredients

purified water

Principal Display Panel - Bottle Label

**HYDROGEN
PEROXIDE**

***First Aid Treatment for Minor Cuts,
and Abrasions***

Package Not Child Resistant

2 fl. oz. (59.15ml)

Manufactured for

Provision Medical Products Palm Desert, CA 92211

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HYDROGEN PEROXIDE

hydrogen peroxide spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 103-3503
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 mL in 1 L

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-3503-1	0.0591 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/29/2014	

Labeler - Provision Medical (036936831)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-3503)

Revised: 8/2014

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