HYDROGEN PEROXIDE- hydrogen peroxide spray Safetec of America, 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 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

Keep out of reach of children.

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 affected area
- if bandaged, let dry first

Inactive ingredients

purified water

PRINCIPAL DISPLAY PANEL - 2 oz. bottle label

NDC 61010-5400-2

Safetec

Hydrogen

Peroxide Spray

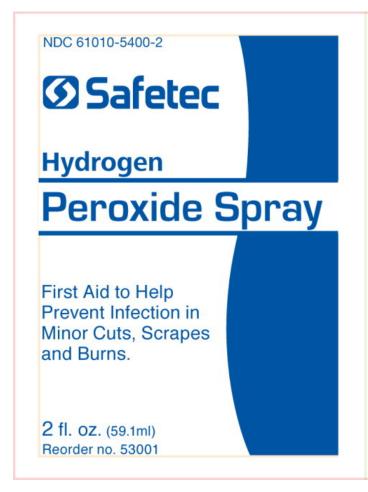
First Aid to Help

Prevent Infection in

Minor Cuts, Scrapes

and Burns.

2 fl. oz. (59.1ml) Reorder no. 53001



Drug Facts Active Ingredients **Purpose** Hydrogen Peroxide 3.0%..... 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 Keep out of reach of children 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 affected area ■ if bandaged, let dry first **Inactive Ingredients** purified water Manufactured by SAFETEC OF AMERICA, Inc. Buffalo, NY 14215 800-456-7077 www.safetec.com

HYDROGEN PEROXIDE

hydrogen peroxide spray

Prod	1	Tnfa	umo	tion
Proa	HCL	11110	rma	HOH

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61010-5400

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthhydrogen peroxide (UNII: BBX060AN9V) (hydrogen peroxide - UNII:BBX060AN9V)hydrogen peroxide30 mg in 1 mL

Inactive Ingredients

Ingredient Name

Strength

water (UNII: 059QF0KO0R)

Packaging						
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:61010-5400-	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 2/16/20 12			
	NDC:61010-5400-	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/16/2012			

Marketing Information						
Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	02/16/2012				

Labeler - Safetec of America, Inc. (874965262)

Establishment					
Name	Address	ID/FEI	Business Operations		
Safetec of America, Inc.		874965262	MANUFACTURE(61010-5400)		

Revised: 2/2012 Safetec of America, Inc.