

HYDROGEN PEROXIDE- hydrogen peroxide solution
Nice-Pak Products, LLC

Swan 871.001/871AA
Hydrogen Peroxide

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 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

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

Adverse reaction

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St. Louis, MO 63114

1-888-593-0593

Pat. D675, 101

Principal Display Panel

Swan ®

Hydrogen

Peroxide

Topical Solution USP

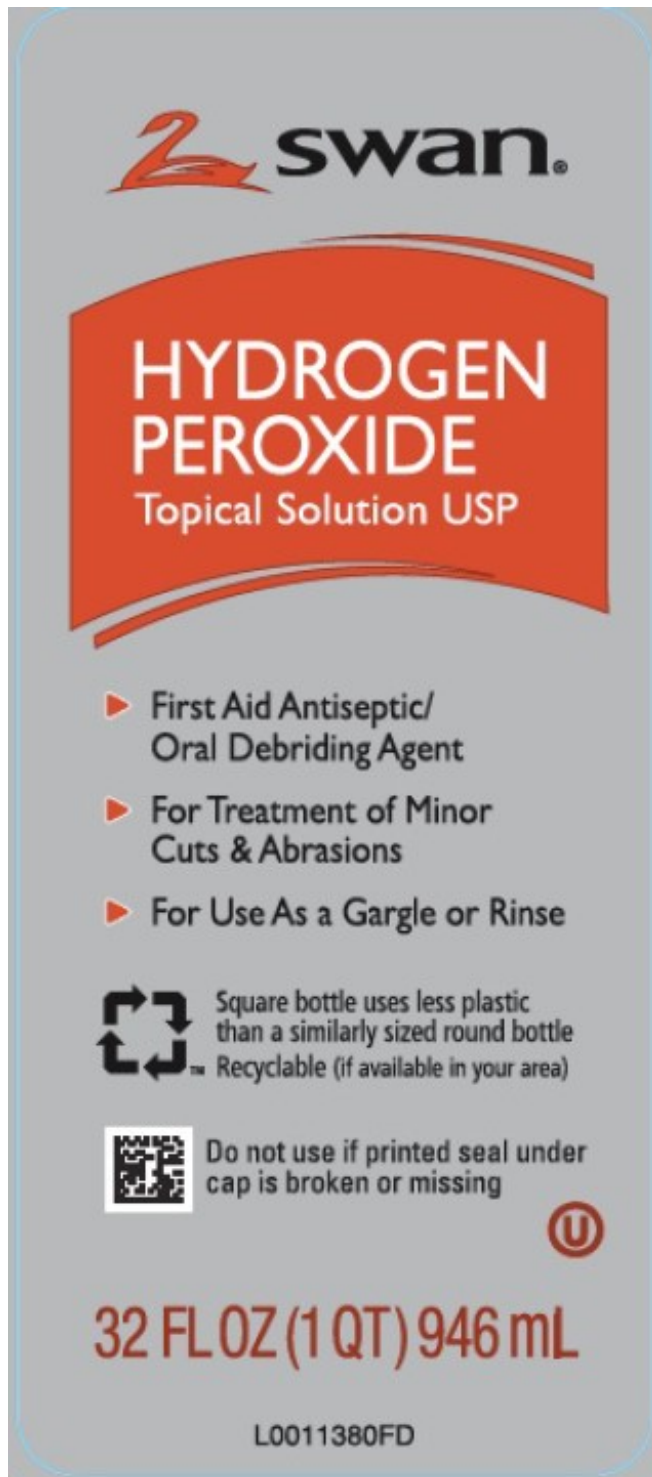
- First Aid Antiseptic/Oral Debriding Agent
- For treatment of minor cuts & abrasions
- For use as a gargle or rinse

Square bottle uses less plastic than a similarly sized round bottle

Recyclable (if available in your area)

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


32 FL OZ (1 QT) 946 mL




swan.

HYDROGEN PEROXIDE
Topical Solution USP

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Oral Debriding Agent
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L0011380FD



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Drug Facts

| Active Ingredient | Purpose |
|-----------------------------------|--|
| Hydrogen peroxide (stabilized) 3% | First aid antiseptic Oral debriding agent |

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Inactive ingredient purified water

L0011380BC
Pat. D675, 101

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HYDROGEN PEROXIDE

hydrogen peroxide solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11344-871

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:11344-871-72 | 295 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 07/09/2017 | |
| 2 | NDC:11344-871-43 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2017 | |
| 3 | NDC:11344-871-45 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2017 | |
| 4 | NDC:11344-871-99 | 237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 07/09/2017 | |
| 5 | NDC:11344-871-34 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2017 | |
| 6 | NDC:11344-871-82 | 177 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 Drug | M003 | 07/09/2017 | |

Labeler - Nice-Pak Products, LLC (119091520)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Nice-Pak Products, LLC | | 119091514 | manufacture(11344-871) |