

HYDROGEN PEROXIDE- hydrogen peroxide solution

Pioneer Associates

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.

CAVALIER HYDROGEN PEROXIDE

Active ingredient (by volume)

Hydrogen Peroxide 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
- on deep or puncture wounds, animal bites or on serious burns

Ask a doctor before use if you have deep puncture wounds, animal bites or serious burns

Stop use and ask a doctor if

- the condition persists or gets worse
- swelling, rash or fever develops
- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens

Keep this and all drugs out of reach of children.

If swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

first aid antiseptic:

- clean affected area
- apply small amount of product on affected area 1-3 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 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 of this product
- children under 2 years of age: consult a dentist or doctor

Other information

- Keep bottle tightly closed and in a dark place at a controlled room temperature.
- Do not shake bottle.
- Hold away from face when opening.

Inactive ingredient

Water

PRINCIPAL DISPLAY PANEL

CAVALIER HYDROGEN PEROXIDE SOLUTION

FIRST AID ANTISEPTIC/ORAL DEBRIDING AGENT

16 FL.OZ (473 mL)

| HYDROGEN PEROXIDE | | | |
|---------------------------------|--|--------------------|----------------|
| hydrogen peroxide solution | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53033-003 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | HYDROGEN PEROXIDE | 3 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|-----------------------------|----------------------|--------------------|
| 1 | NDC:53033-003-08 | 100 mL in 1 BOTTLE, PLASTIC | | |
| 2 | NDC:53033-003-01 | 119 mL in 1 BOTTLE, PLASTIC | | |
| 3 | NDC:53033-003-02 | 178 mL in 1 BOTTLE, PLASTIC | | |
| 4 | NDC:53033-003-09 | 200 mL in 1 BOTTLE, PLASTIC | | |
| 5 | NDC:53033-003-03 | 237 mL in 1 BOTTLE, PLASTIC | | |
| 6 | NDC:53033-003-10 | 250 mL in 1 BOTTLE, PLASTIC | | |
| 7 | NDC:53033-003-11 | 266 mL in 1 BOTTLE, PLASTIC | | |
| 8 | NDC:53033-003-04 | 295 mL in 1 BOTTLE, PLASTIC | | |
| 9 | NDC:53033-003-05 | 354 mL in 1 BOTTLE, PLASTIC | | |
| 10 | NDC:53033-003-06 | 414 mL in 1 BOTTLE, PLASTIC | | |
| 11 | NDC:53033-003-07 | 473 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 08/24/2012 | |

Labeler - Pioneer Associates (012604336)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|---------|-----------|------------------------|
| Anicare Pharmaceuticals Pvt. Ltd | | 916837425 | manufacture(53033-003) |

Revised: 8/2012

Pioneer Associates