

**HYDROGEN PEROXIDE- hydrogen peroxide solution**  
**Hydrox Laboratories**

-----  
**SOLUTION OF  
HYDROGEN PEROXIDE  
3% USP 10 VOLUME**

***Drug Facts***

**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, mucous, 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 1 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 area 1 to 3 times daily

- 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 of this product
  - children under 2 years of age: consult a dentist or doctor

### **Other information**

Keep tightly closed in a cool dark place. Do not shake bottle. Hold away from face when opening.

### **Inactive ingredient**

Purified Water

### **PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

#### **OPTIMATES**

HYDROX  
CHEMICALS  
TRADEMARK  
SINCE 1913

#### ***Hydrox***

NDC 10565-001-16

**SOLUTION OF  
HYDROGEN PEROXIDE  
3% USP 10 VOLUME**

**3%**

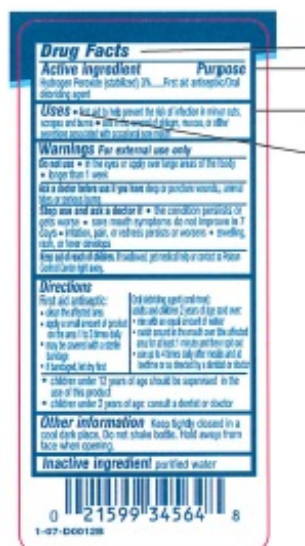
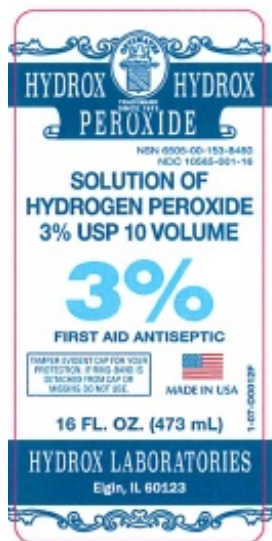
TAMPER EVIDENT CAP FOR YOUR PROTECTION.

IF RING-BAND IS DETACHED FROM CAP OR MISSING DO NOT USE.

**FIRST AID ANTISEPTIC**

**Made in USA**

**16 FL. OZ. (473 mL)**



# HYDROGEN PEROXIDE

hydrogen peroxide solution

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10565-001 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| <b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | HYDROGEN PEROXIDE | 3 mL in 100 mL |

## Inactive Ingredients

| Ingredient Name                 | Strength |
|---------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R) |          |

## Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10565-001-04 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 09/01/1993           |                    |
| 2 | NDC:10565-001-08 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 09/01/1993           |                    |
| 3 | NDC:10565-001-16 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 09/01/1993           |                    |
| 4 | NDC:10565-001-32 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 09/01/1993           |                    |
| 5 | NDC:10565-001-99 | 3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/1993           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M003                                     | 09/01/1993           |                    |

**Labeler** - Hydrox Laboratories (025164302)

**Registrant** - Hydrox Laboratories (025164302)

## Establishment

| Name                | Address | ID/FEI    | Business Operations   |
|---------------------|---------|-----------|---|
| Hydrox Laboratories |         | 025164302 | manufacture(10565-001) , label(10565-001) , pack(10565-001) |

Revised: 10/2023

Hydrox Laboratories