

## **HYDROGEN PEROXIDE- hydrogen peroxide solution**

### **Cardinal Health**

*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.*

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### **Cardinal Health Hydrogen Peroxide 450.000/450AA**

#### **Active ingredient**

Hydrogen peroxide (stabilized) 3%

#### **purpose**

First Aid Antiseptic

Oral debriding agent

#### **Use**

- 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 occassional 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 pucture 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 the product on the affected area 1 to 3 times a day
- may be covered with a sterile bandage
- if bandage, let dry first

Oral Debriding Agent:

- adults, children over 2 years of age
- mix with equal amount of water
- swish around in the mouth over the affected area for at least 1 minute, then spit out
- use up to 4 times daily after meals and at bedtime
- 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**

water

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Waukegan, IL 60085 USA

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## **Principal display panel**

NDC 63517-450-43

Hydrogen Peroxide 3%

first aid antiseptic

oral debriding agent

DO NOT USE IF PACKAGE OPENED OR DAMAGED

TEMPERATURE LIMITATION 68°F - 77°F 20°C - 25°C

Not Made with Natural Rubber Latex

For Individual, Professional, and Hospital Use

Cat. AS-HPL16

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CardinalHealth

16 FL OZ (1 PT) 473 mL

NDC: 63517-450-43

# Hydrogen Peroxide 3%

first aid antiseptic  
oral debriding agent



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**Cardinal Health™**

16 FL OZ (1 PT) 473 mL

L0015145FB

## HYDROGEN PEROXIDE

hydrogen peroxide solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63517-450
<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	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:63517-450-26	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	
2	NDC:63517-450-34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	
3	NDC:63517-450-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2015	

**Labeler -** Cardinal Health (961027315)

**Registrant -** Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63517-450)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(63517-450)

Revised: 9/2023

Cardinal Health