

**HCS HYDROGEN PEROXIDE 3%- hydrogen peroxide liquid
Concordance Healthcare Solutions, LLC.**

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.

**Hydrogen Peroxide
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

HCS

NDC 83506-001-16

***Solution of
Hydrogen Peroxide
3% USP 10 Volume***

FIRST AID ANTISEPTIC

ORAL DEBRIDING AGENT

- *For treatment of minor cuts, scrapes, and burns*
- *For use as a gargle or rinse*
- *For external use only*

SEALED FOR YOUR PROTECTION

IF THE SEAL IS BROKEN OR MISSING DO NOT USE

16 FL OZ (1 PT) 473 mL



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Manufactured for: Concordance Healthcare Solutions, LLC
85 Shaffer Park Drive, Tiffin, OH 44883 • 1-855-241-1773
Made in USA #902-HCS0202 Rev. 0

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Reorder No. HCS0202



(01) 0 0810132 04025 2

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Inactive ingredient purified water

HCS HYDROGEN PEROXIDE 3%

hydrogen peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83506-001
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:83506-001-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2023	
2	NDC:83506-001-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2023	
3	NDC:83506-001-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2023	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/14/2023		

Labeler - Concordance Healthcare Solutions, LLC. (080220245)

Establishment

Name	Address	ID/FEI	Business Operations
Ken Prima Cosmeceuticals SDN BHD		865792209	MANUFACTURE(83506-001)

Revised: 8/2023

Concordance Healthcare Solutions, LLC.