

HYDROGEN PEROXIDE- hydrogen peroxide liquid
BROSANT GROUP 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.

Active Ingredient

Active Ingredient
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

Ask a doctor before use if you have

- deep puncture wounds, animal bites or serious burns

Stop use and ask a doctor if

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

Keep out of reach of children

In case of ingestion, get medical help or contact a Poison Control Center (1-800-222-1222) right away

Directions

For use as a first aid antiseptic

- clean affected area
- if bandaged, let dry first
- apply small amount of product on affected area 1-3 times a day
- may be covered with a sterile bandage

For use as an oral debriding agent (oral rinse):

- adults and children 2 years of age and over:
 - mix with and equal amount of water
 - swish around in the mouth over affected area for at least 1 minute and then spit out. Do not swallow.

-use up 4 times daily after meals and at bedtime or as directed by a dentist or doctor

children under 12 years should be supervised in the use of this product

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

Other information

-keep tightly closed and in a dark place at room temperature

-do not shake bottle. Hold away from face when opening

Inactive ingredient

purified water

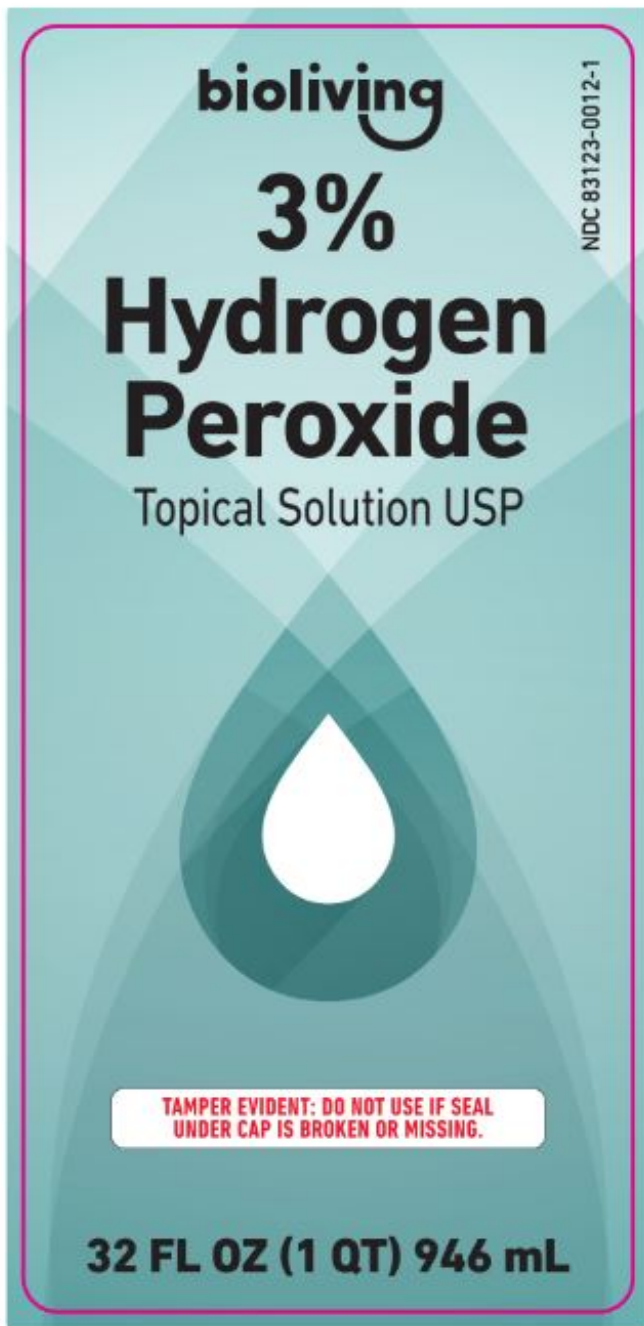
bioliving

3% hydrogen peroxide

topical solution USP

Tamper evident: do not use if seal under cap is broken or missing

32 FL OZ (1 QT) 946 mL



HYDROGEN PEROXIDE

hydrogen peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83123-0012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	3 mL in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	97 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83123-0012-1	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/16/2023	

Labeler - BROSANT GROUP LLC (117037683)

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