

DYNAREX HP 3- hydrogen peroxide liquid

Dynarex Corporation

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 3%

Active Ingredient	Purpose
Hydrogen peroxide 3% v/v	Antiseptic Oral debriding agent

PURPOSE

First aid to help prevent the risk of infection in:

- minor cuts
- scrapes
- burns
- aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth.

WARNINGS

- **For external use only**
- **Ask a doctor before use if you have** deep puncture wounds, animal bites or serious burns.
- **Stop use and ask a doctor if** condition persist or gets worse.
- Sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling rash or fever develops

INDICATIONS & USAGE

Do not use:

- in the eyes or over large areas of the body
- longer than 1 week

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION

DIRECTIONS as a First Aid Antiseptic:

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

DIRECTIONS as a Oral Debriding Agent:

Adults, children over 2 years of age:

- mix with an equal amount of water
- swish around the mouth in 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

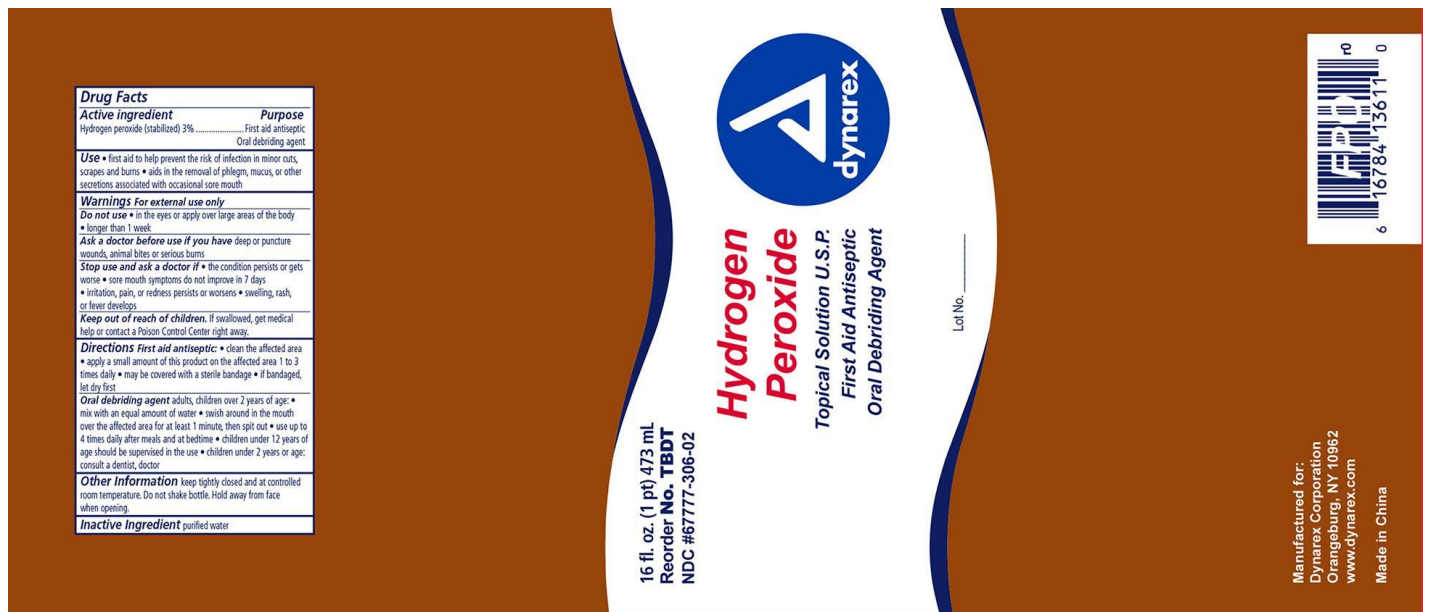
Inactive Ingredient

- Water

PRINCIPAL DISPLAY PANEL

DYNAREX 3% Hydrogen Peroxide

Hydrogen Peroxide.jpg



DYNAREX HP 3

hydrogen peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE -	HYDROGEN	2.65 mL

UNII:BBX060AN9V)	PEROXIDE	in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-306-01	118 mL in 1 BOTTLE		
2	NDC:67777-306-02	454 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/29/2014	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(67777-306)

Revised: 1/2014

Dynarex Corporation