BLOSSOM HP 3- hydrogen peroxide liquid Blossom Pharmaceuticals

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 Hydrogen peroxide 3% v/v Purpose 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 occassional 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.

IIf 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 dentis or doctor

OTHER INFORMATION

- keep tightly closed and at controlled room temperature.
- do not shake bottle
- Hold away from face when opening

INACTIVE INGREDIENT

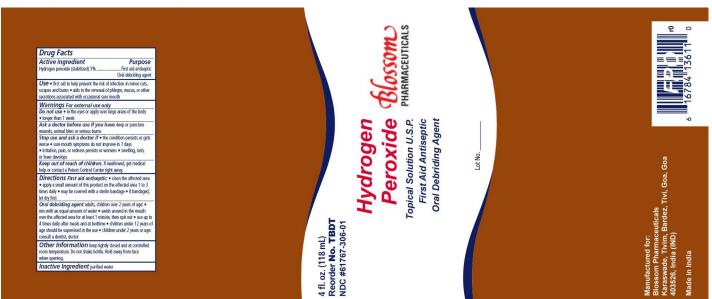
Inactive Ingredient

• Water

PRINCIPAL DISPLAY PANEL

Blossom Pharmaceuticals 3% Hydrogen Peroxide

Hydrogen Peroxide BP.jpg



BLOSSOM HP 3

hydrogen peroxide liquid

Product Information									
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:61767-306					
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
Ingredient Name			Basis of Streng	th Strength					
HYDROGEN PEROXIDE (UNII: BBX06	HYDRO GEN	2.65 mL							

UNII:BBX060AN9V)			PEROX	KIDE	in 100 mL					
Iı	Inactive Ingredients									
Ingredient Name					Strength					
W	WATER (UNII: 059QF0K00R)									
Packaging										
#	Item Code	Package Description	Marketing	g Start Date	Ma	rketing End Date				
1	NDC:61767-306-01	118 mL in 1 BOTTLE								
2	NDC:61767-306-02	454 mL in 1 BOTTLE								
Marketing Information										
	Marketing Category	Application Number or Monograph Citation Mark		Marketing Sta	art Date	Marketing End Date				
		part356 01/								
0	TC monograph not final	part356		0 1/29 /20 14						

Labeler - Blossom Pharmaceuticals (677381470)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(61767-306)

Revised: 1/2014

Blossom Pharmaceuticals