PHENOL- phenol spray Perrigo New York Inc

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.

Perrigo Phenol 1.4% Drug Facts

Active ingredient

Phenol 1.4%

Purpose

Oral anesthetic/analgesic

Uses

For the temporary relief of occasional minor irritation, pain, sore mouth and sore throat.

Warnings

Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or give to children under 3 years of age.

When using this product

do not use more than directed

Stop use and ask a doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

Adults and children 3 years of age and older:

- apply to the affected area (one spray)
- allow to remain in place for at least 15 seconds, then spit out
- use every 2 hours or as directed by a doctor or dentist. Children under 12 years of age should be supervised in the use of this product.

Other information

• store at 20-25°C (68-77°F)

Inactive ingredients

FD&C red #40, flavor, glycerin, purified water, saccharin sodium

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Chloraseptic® active ingredient

Phenol 1.4%

Sore Throat Spray

Oral Anesthetic Analgesic

Alcohol Free

Aspirin Free

Sugar Free

Cherry Flavor

See New Directions





Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENOL (PHENOL)	PHENOL	1.4 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40			
GLYCERIN			
WATER			
SACCHARIN SO DIUM			

Product Characteristics				
Color	RED (clear)	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:45802-327-82	177 mL in 1 BOTTLE, SPRAY			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	12/09/2010		

Labeler - Perrigo New York Inc (078846912)

Revised: 11/2012 Perrigo New York Inc