

SORE THROAT- phenol spray
We Care Distributor 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.

Sore Throat

Active ingredient

Phenol 1.4%

Purpose

Oral anesthetic/analgesic

Uses

- For the temporary relief of occasional minor throat:
- 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 administer to children under 3 years of age unless directed by a doctor.

When using this product

- do not exceed recommended dose
- do not use for more than 2 days, Use only as directed
- use of this container by more than one person may spread infection

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 doctor before use.

Keep out of reach of children.

In case of overdose or accidental poisoning, get medical help or contact a Poison Control Center right away.

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
- **Children under 3 years of age:** consult a doctor or dentist
- Before using the first time, remove the protective neck band and its dust cap from the tip. To spray, hold bottle straight up and press on the nozzle with index finger without tilting head. Fully depress pump all the way down with a firm even stroke. Wipe nozzle dry.

Other information

- store at room temperature
- check expiration date before using
- retain carton for future reference

Inactive ingredients

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

Principal Display Panel

Compare to the Active Ingredient in Chloraseptic

FAST RELIEF

SORE THROAT SPRAY

PHENOL / ORAL ANESTHETIC

CHERRY FLAVOR

Instant-Acting

Relieves Sore Throat

See New Directions



SORE THROAT

phenol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-035
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	1.4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-035-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/23/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/23/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
PURINE PHARMA LLC		019950491	manufacture(70005-035)

Revised: 9/2016

We Care Distributor Inc.