PHENOL- sore throat spray spray
PURINEPHARMA 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.

SORE THROAT SPRAY

Active Ingredient:
Phenol 1.4%

Purpose: Oral Anesthetic/ Analgesic

Uses

- For the temporary relief of occasional minor throat:
  1. Irritation
  2. Pain
  3. Sore Mouth
  4. Sore Throat

Warnings

Sore Throat Warnings:
Severe and persisttent 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.

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

Stop use and ask doctor or dentist if sore throat symptoms do not improve in 7 days Irritation, pain or redness persists or worsens. Swelling, rash or fever develops.

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

Keep out of reach of children. In case of overdose or accidental poisioning, 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 dust cap from the tip. To spray, hold bottle straight up and press on the nozzle with index finger without tiltting head. Fully depress pump all the way down with a firm even stroke. Wipe nizzle dry.

Other information

- Store at room temperature
- **Temper Evident:** Do not use if printed neck band is broken or missing

- Check expiration date before using

Inactive ingredients are: Sodium Saccharin, Glycerin, Purified water, FD&C red# 40, Cherry Flavour.

Manufactured in USA by
Purinepharma LLC

5 County Route 42
Massena, NY 13662
A MEDIBEST Brands Company

Questions: www.purinepharma.com
Tel: 1-315-705-4030
NDC: 58599-008-06

PHENOL

sore throat spray spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58599-008
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	1.4 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CHERRY (UNII: BUC5I9595W)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58599-008-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:58599-008-06	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/01/2015	

Labeler - PURINEPHARMA LLC (019950491)

Registrant - PURINEPHARMA LLC (019950491)

Establishment

Name	Address	ID/FEI	Business Operations
PURINEPHARMA LLC		019950491	MANUFACTURE(58599-008)

Revised: 6/2015 PURINEPHARMA LLC