

CARE ONE SORE THROAT- phenol spray
American Sales Company

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.

American Sales Company Sore Throat Spray 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.

Children under 3 years of age: consult a doctor or dentist

Other information

- store at 20-25°C (68-77°F)

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



CARE ONE SORE THROAT			
phenol spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-328
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
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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:41520-328-30	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	11/19/2003	

Labeler - American Sales Company (809183973)

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