

SORE THROAT CHERRY- phenol spray
Cardinal Health (Leader) 49781

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.

Drug Facts

Active ingredient

Phenol 1.4%

Purpose

Oral Anesthetic/Analgesic

Uses

temporarily relieves sore throat pain, sore mouth, pain associated with canker sores, minor mouth irritation

Warnings

Sore throat warning: Severe or persistent sore throat or sore throat that occurs with high fever, headache, nausea, and vomiting may be serious. Ask a doctor right away. 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 if

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

If pregnant or breast-feeding,
ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- apply to affected area
- use every 2 hours
- allow to remain in place for at least 15 seconds, then spit out

| age | dose |
|---------------------------------------|-------------------------------------|
| adults and children 12 years and over | for each application, spray 5 times |

| | |
|------------------------|---|
| children 3 to 11 years | should be supervised in use of this product for each application, spray 3 times |
| children under 3 years | ask a doctor or dentist |

Other information

- store at 20°-25°C (68°-77°F). Do not refrigerate.

Inactive ingredients

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

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Chloraseptic® active ingredient*

Cherry Flavor

Sore Throat Spray

Phenol/Oral Anesthetic

Instant Acting/Relieves Sore Throat

Relief of Minor Sore Throat and Mouth Irritation

Alcohol 0.10%

FL OZ (mL)

*This product is not manufactured or distributed by Prestige Brands, Inc., owner of the registered trademark Chloraseptic®.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED WRAP AROUND THE CAP IS BROKEN OR TORN.

DISTRIBUTED BY: CARDINAL HEALTH DUBLIN, OHIO 43017

CIN 4957643

www.myleader.com

1-800-200-6313

Package Label

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All Leader® brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund

DISTRIBUTED BY: CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 4957643
www.myleader.com 1-800-360-6313

NDC 49781-098-06



CHERRY FLAVOR

Sore Throat Spray

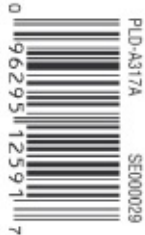
Phenol/Oral Anesthetic

Instant Acting/Relieves Sore Throat

Relief of Minor Sore Throat and Mouth Irritation

Alcohol 0.10%

6 FL OZ (177 mL)



| Drug Facts | |
|---|---|
| Active ingredient | Purpose |
| Phenol 1.4% | Oral Anesthetic/Analgesic |
| Uses temporarily relieves sore throat pain, sore mouth, pain associated with canker sores, minor mouth irritation | |
| Warnings | |
| Sore throat warning: Severe or persistent sore throat or sore throat that occurs with high fever, headache, nausea, and vomiting may be serious. Ask a doctor right away. 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 if <ul style="list-style-type: none"> swelling, rash or fever develops irritation, pain or redness persists or worsens sore mouth symptoms do not improve in 7 days difficulty in breathing occurs | |
| If pregnant or breast-feeding, ask a health professional before use. | |
| Keep out of reach of children. | |
| In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. | |
| Directions <ul style="list-style-type: none"> apply to affected area use every 2 hours allow to remain in place for at least 15 seconds, then spit out | |
| age | dose |
| adults and children 12 years and over | for each application, spray 5 times |
| children 3 to 11 years | should be supervised in use of this product for each application, spray 3 times |
| children under 3 years | ask a doctor or dentist |
| Other information <ul style="list-style-type: none"> store at 20°-25°C (68°-77°F). Do not refrigerate. | |
| Inactive ingredients alcohol, FD&C red #40, glycerin, natural & artificial flavor, purified water, saccharin sodium | |
| Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST | |

Leader Sore Throat Spray

SORE THROAT CHERRY

phenol spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49781-098 |
| 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 |
|-------------------------------------|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0K00R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |

Product Characteristics

| | | | |
|--------------|-----|--------------|--|
| Color | RED | Score | |
| Shape | | Size | |

| Flavor | CHERRY | Imprint Code | | |
|------------------------------|--|--|----------------------|--------------------|
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:49781-098-06 | 177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 07/31/2014 | 12/31/2020 |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC MONOGRAPH NOT FINAL | part356 | 07/31/2014 | 12/31/2020 | |

Labeler - Cardinal Health (Leader) 49781 (097537435)

Revised: 11/2019

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