# DRX CHOICE SORE THROAT MENTHOL FLAVOR- phenol spray RARITAN PHARMACEUTICALS 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.

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#### **DRx Choice Sore Throat Spray Sugar Free**

#### **Active ingredient**

Phenol 1.4%

### **Purpose**

Oral pain reliever

#### Uses

For the temporarily relieves 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 a doctor promptly. Do not use more than 2 days or administer to children under 6 years of age unless directed by doctor.

## When using this product,

do not exceed recommended dosage.

# 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 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 (1-800-222-1222).

#### **Directions**

### Adults and children 12 year of age and older:

Apply to 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 use of this product.
- Children under 6 years of age: Ask a doctor or dentist

#### Other information

- Store at room temperature
- Check expiration date before using.

## Inactive ingredients

FD&C Green #3, D&C Green #5, FD&C Yellow #10, flavor, glycerin, purified water, sucralose.

#### **Questions or comments?**

1-866-467-2748

## **Principal Display Panel**

DRx Choice®

NDC# 68163-307-06

\*Compare to the active ingredient in Chloraseptic®

Sore throat spray

Phenol/Oral Pain Reliever

- Fast Acting
- Numbs on Contact

**SUGAR-FREE** 

**ASPIRIN-FREE** 

Menthol Flavor

Naturally and Artificially Flavored

6 FL OZ. (177 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 shrink band is broken or torn.





#### Drug Facts (continued)

Keep out of reach of children. If more than used for minor mouth or throat pain is accidentally swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

#### Directions

■ Adults and children 12 years of age and older:
Apply to 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 6 years to under 12 years of
age: Should be supervised in the use of this
product. ■ Children under 6 years: Consult a
doctor or dentist.

Other information ■ Store at room temperature. ■ Check expiration date before using.

Inactive ingredients FD&C Green No. 3, D&C Green No. 5, FD&C Yellow No. 10, flavor, glycerin, purified water, sucralose

Questions or comments? 1-866-467-2748

## DRX CHOICE SORE THROAT MENTHOL FLAVOR

phenol spray

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68163-307

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)

PHENOL

1.4 g in 100 mL

| _                                    |          |
|--------------------------------------|----------|
| Ingredient Name                      | Strength |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)  |          |
| D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)   |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) |          |
| GLYCERIN (UNII: PDC6A3C0OX)          |          |
| WATER (UNII: 0590F0KO0R)             |          |

| Product Characteristics |               |              |  |  |
|-------------------------|---------------|--------------|--|--|
| Color                   | GREEN (clear) | Score        |  |  |
| Shape                   |               | Size         |  |  |
| Flavor                  | MENTHOL       | Imprint Code |  |  |
| Contains                |               |              |  |  |

| F | Packaging            |  |                         |                       |
|---|----------------------|--|-------------------------|-----------------------|
| # | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:68163-<br>307-06 | 177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 10/17/2022              |                       |

| Marketing Information   |   |                         |                       |  |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category   | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC monograph not final | part356                                     | 10/17/2022              |                       |  |
|                         |   |                         |                       |  |

# Labeler - RARITAN PHARMACEUTICALS INC (127602287)

Revised: 9/2023 RARITAN PHARMACEUTICALS INC