# **ULCEREASE-** phenol 0.6% anesthetic oral rinse rinse Crown Laboratories

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# **Ulcerease Anesthetic Mouth Rinse**

0.6 % Phenol

Anesthetic/Analgesic

Temporary relief of occasional minor irritation, pain, sore mouth, sore throat, canker sores and teething.

- Keep out of reach of children.
  Not for ingestion.
- If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly.
- Keep out of reach of children.
- Shake well prior to use.
- Use full strength as a mouth rinse, rinsing affected area for 15 seconds and spitting out the remainder of the product.
- For upper throat, gargle for 15 seconds and spit out.
- For adults and children over 12 years of age use every 2 hours or as needed; do not use more than 12 times per day.
- Children ages 4 months to under 12 years of age, apply to affected area with clean swab. Use up to 6 times daily or as directed by physician or dentist.
- For teething and hard to reach areas, apply directly to area with tip of clean swab, repeat up to 6 times daily.

Store at room temperature 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

Glycerin, Purified Water, Sodium Bicarbonate and Sodium Borate.

TAMPER RESISTANT SEAL-IF SEAL IS BROKEN DO NOT USE.

NDC 0316-0100-06

# Ulcerease ®

Anesthetic Mouth Rinse

Quick pain relief for mouth and upper throat irritations

CONTAINS: NO SUGAR, NO ALCOHOL, NO ARTIFICIAL DYES OR COLORINGS. PLEASANT TO USE.

Manufactured and Distributed by: Crown Laboratories Inc.,

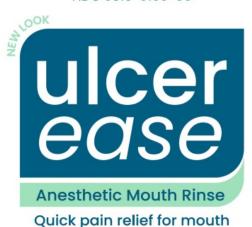
Johnson City, TN 37604

800.334.4286

www.crownlaboratories.com

P6028.03

NDC 0316-0100-06



6 fl oz (178 ml)

and upper throat irritations

### **Drug Facts**

### **Active Ingredient**

**Purpose** 

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Anesthetic/Analgesic

 $\pmb{\mathsf{Uses}}$  . Temporary relief of occasional minor irritation, pain, sore mouth, sore throat, canker sores and teething.

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Other information Store at room temperature 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

Inactive ingredients Glycerin, Purified Water, Sodium Bicarbonate and Sodium Borate.

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### **ULCEREASE**

phenol 0.6% anesthetic oral rinse rinse

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Product Type	HUMAN OTC DRUG	Itam Cada (Saurca)	NDC:0316-0100
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0310-0100

**ORAL Route of Administration** 

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	6 mg in 1 mL

# **Inactive Ingredients**

Ingredient Name	Strength	
-	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM BORATE (UNII: 91MBZ8H3QO)		
GLYCERIN (UNII: PDC6A3C0OX)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		

## **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-0100- 06	178 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/1977	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	03/28/1977	08/29/2025

# **Labeler -** Crown Laboratories (079035945)

# **Registrant -** Crown Laboratories (079035945)

Establishment				
Name	Address	ID/FEI	Business Operations	
Crown Laboratories		079035945	manufacture(0316-0100)	

Revised: 12/2023 Crown Laboratories