

PHYLORINOL- phylorinol liquid Schaffer Laboratories

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.

Label



OTC - ACTIVE INGREDIENT SECTION

Drug Facts

Active Ingredient

Phenol 0.6%.....Oral Pain Reliever

Uses

- temporary relief of occasional minor irritation, pain, sore mouth, and sore throat.

Warnings

If used for sore throat:

Consult a doctor promptly if sore throat is

- severe or persists more than 2 days
- accompanied by :
 - rash
 - swelling
 - fever
 - headache
 - nausea
 - vomiting

Unless directed by a doctor do not administer to children under 3 years of age.

If used for sore mouth:

See your dentist or doctor promptly if

- sore mouth symptoms do not improve in 7 days.
- irritation, pain, or redness persists or worsens

Stop use and ask a doctor if persistent or severe inflammation occurs, which may indicate Iodine or Phenol sensitivity.

Keep out of reach of children.

If more than what remains in mouth after spitting out is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: gargle or swish around the mouth for at least 15 seconds and then spit out. Use every 2 hours or as directed by a dentist or doctor.
- Children 6 to under 12 years of age: apply 10 milliliters to the affected area, gargle or swish around the mouth for at least 15 seconds then spit out. Use every 2 hours or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product.
- Children under 6 years of age: consult a dentist or doctor

Other information

- store at 15°-30°C (59°-86°F)

Inactive ingredients

boric acid, carrageenan, chlorophyllin copper complex sodium, methyl salicylate, purified water, sodium chloride, sorbitol, strong iodine solution.



OTC - PURPOSE SECTION

Uses

- temporary relief of occasional minor irritation, pain, sore mouth, and sore throat.



OTC - KEEP OUT OF REACH OF CHILDREN SECTION

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If more than what remains in mouth after spitting out is accidentally swallowed, get medical help or contact a Poison Control Center right away.



INDICATIONS & USAGE SECTION

Other information

- store at 15°-30°C (59°-86°F)



WARNINGS SECTION

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DOSAGE & ADMINISTRATION SECTION

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INACTIVE INGREDIENT SECTION

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PHYLORINOL

phylorinol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54061-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	.25 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54061-101-01	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/05/2014	

Labeler - Schaffer Laboratories (018440696)**Registrant** - Schaffer Laboratories (018440696)**Establishment**

Name	Address	ID/FEI	Business Operations
Schaffer Laboratories		018440696	manufacture(54061-101)