SUCRETS- dyclonine hcl, menthol, and pectin lozenge Insight Pharmaceuticals LLC

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.

Sucrets Sore Throat, Cough & Dry Mouth

Drug Facts

Active ingredients (per lozenge)

Active ingredients (per lozenge)	Purpose
Dyclonine hydrochloride, 2 mg	Oral anesthetic/Analgesic
Menthol, 5 mg	Cough suppressant
Pectin, 6 mg	Demulcent

Uses

Temporarily relieves:

- occasional minor irritation, pain, sore throat, and sore mouth
- cough associated with a cold or inhaled irritants
- for protection of irritated areas in sore mouth and throat

Warnings

Sore through warning: if sore throat is severe, persists for more than 2 days, is accompanied by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly.

Ask a doctor before use if you have

- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- cough that occurs with too mych phlegm (mucus)

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash, or fever develops
- cough lasts more than 7 days, comes back, or occurs with fever, or persistent headache. These could be signs of a serious condition.

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

- Do not use more than directed
- adults and children 4 years of age and older: Dissolve 1 lozenge slowly in the mouth. May be repeated every 2 hours as needed or as directed by a doctor or dentist

• children under 4 years of age: consult a doctor or dentist

Other information

- store between 15°-30°C (59°-86°F)
- use only if lozenge blister seals are unbroken
- contains FD&C Yellow No.5 (tartrazine) as a color additive

Inactive ingredients

corn syrup, FD&C yellow no.5, FD&C yellow no.6, honey, lemon oil, propylene glycol, sucrose, tartaric acid, water

Questions

1-800-344-7239

Sucrets.com

PRINCIPAL DISPLAY PANEL

Sucrets Sore Throat, Cough & Dry Mouth

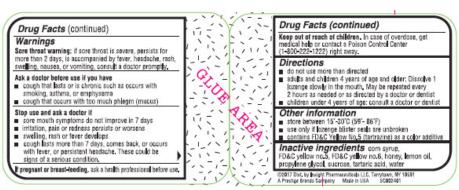
Dyclonine/Oral Anesthetic

Menthol/Cough Suppressant

Pectin/Dry Mouth

18 lozenges





SUCRETS

dyclonine hcl, menthol, and pectin lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-567

Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DYCLONINE HYDRO CHLORIDE (UNII: ZEC193879Q) (DYCLONINE - UNII: 078 A24Q30O)	DYCLONINE HYDROCHLORIDE	2 mg
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	5 mg

WATER (UNII: 059QF0KO0R)

Inactive Ingredients			
Ingredient Name	Strength		
CORN SYRUP (UNII: 9G5L16BK6N)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
HO NEY (UNII: Y9 H1V576 FH)			
LEMON OIL (UNII: 19 GRO 824LL)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SUCROSE (UNII: C151H8M554)			
TARTARIC ACID (UNII: W4888I119H)			

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	19 mm
Flavor	LEMON ((Honey Lemon))	Imprint Code	
Contains			

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:63736-567-18	18 in 1 CAN; Type 0: Not a Combination Product	11/04/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/0 4/20 14	

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 12/2017 Insight Pharmaceuticals LLC