SUCRETS COMPLETE VAPOR CHERRY- dyclonine hydrochloride and menthol lozenge Insight Pharmaceuticals

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 COMPLETE

Active ingredient (per lozenge)

Dyclonine Hydrochloride 3.0 mg Menthol 6.0 mg

Purpose

Oral Anesthetic/Analgesic Cough Suppressant

Uses

temporarily relieves:

- occasional minor irritation, pain, sore throat and sore mouth
- cough associated with a cold or inhaled irritants

Warnings

Sore throat warning

Severe or persistent sore throat or sore throat that occurs with or is followed by high fever, headache, rash, swelling and nausea may be serious. Ask doctor right away. Do not use more than 2 days or give to children under 2 years of age unless directed by a doctor.

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 much 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 right away.

Directions

• adults and children 2 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 2 years of age: consult a doctor or dentist.

Other Information

Avoid storing at high temperature (greater than 100°F).

Use only if lozenge blister seals are unbroken

Inactive ingredients

Corn Syrup, Sucrose, Water, Propylene Glycol, Citric Acid, Zinc Gluconate, Tartaric Acid, Sodium Ascorbate, Acesulfame Potassium, Ascorbic Acid, Cherry Flavor, FD&C Red #40.

QUESTIONS

CALL 1-800-344-7239 www.insightpharma.com

DIST. BY: INSIGHT PHARMACEUTICALS CORP.

LANGHORNE, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 18 Lozenges Container

GUARANTEED...Made Stronger To Last Longer!®

SUCRETS® COMPLETE

DYCLONINE / ORAL ANESTHETIC • MENTHOL / COUGH SUPPRESSANT

- Suppresses Cough
- Serious Sore Throat Relief
- Cools Nasal Passages
- Fights Bad Breath

PLUS Vitamin C and Zinc

18 LOZENGES

VAPOR CHERRY

65970B



PRINCIPAL DISPLAY PANEL - 24 Lozenges Container

GUARANTEED...Made Stronger To Last Longer!®

SUCRETS® COMPLETE

DYCLONINE / ORAL ANESTHETIC • MENTHOL / COUGH SUPPRESSANT

- Suppresses Cough
- Serious Sore Throat Relief
- Cools Nasal Passages

PLUS
Vitamin C and Zinc

BONUS 33% MORE
24 Lozenges for the price of 18 Lozenges
24 LOZENGES
VAPOR CHERRY

66019A





PRINCIPAL DISPLAY PANEL - Back Label



Warnings Sere threat warning: Severe or persistent sore threat or sore threat that occurs with or is followed by high fever, headache, rash, swelling and neusea may be serious. Ask doctor right away. Do not use more than 2 days or give to children under 2 years of age unless directed by a doctor. 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 much phlegm (mucus)

Drug Facts (continued)

Stop use and ask a doctor if

sore mouth symptoms do not improve in 7 days
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swelling, rash or fever develops
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with fever, or persistent beadache. These could be
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Drug Facts (continued)

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Other Information

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SUCRETS COMPLETE VAPOR CHERRY

dyclonine hydrochloride and menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-920
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Dyclonine Hydrochloride (UNII: ZEC193879Q) (Dyclonine - UNII:078A24Q30O)	Dyclonine Hydrochloride	3 mg	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	6 mg	

Inactive Ingredients			
Ingredient Name	Strength		
Corn Syrup (UNII: 9G5L16BK6N)			
Sucrose (UNII: C151H8M554)			
Water (UNII: 059QF0KO0R)			
Propylene Glycol (UNII: 6DC9Q167V3)			
Citric Acid Monohydrate (UNII: 2968PHW8QP)			
Zinc Gluconate (UNII: U6WSN5SQ1Z)			
Tartaric Acid (UNII: W4888I119H)			
Sodium Ascorbate (UNII: S033EH8359)			
Acesulfame Potassium (UNII: 230 V73Q5G9)			
Ascorbic Acid (UNII: PQ6CK8PD0R)			
FD&C Red no. 40 (UNII: WZB9127XOA)			

Product Characteristics			
Color	RED	Score	no score
Shape	ROUND	Size	19 mm
Flavor	CHERRY	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-920-18	18 in 1 CANISTER		
2	NDC:63736-920-24	24 in 1 CANISTER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/31/2009	

Labeler - Insight Pharmaceuticals (176792315)

Revised: 8/2009 Insight Pharmaceuticals