HALLS SUGAR FREE BLACK CHERRY- menthol lozenge Kraft Foods Global, 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.

Drug Facts

Active Ingredient

(in each drop) Menthol 3.7 mg

Purpose

Cough suppressant, Oral anesthetic

Uses

temporarily relieves:

- cough due to a cold
- occasional minor irritation or sore throat

Warnings

Sore Throat Warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.
- sore mouth does not improve in 7 days
- irritation, pain, or redness persists or worsens

Keep out of reach of children

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Directions

- adults and children 5 years and over: dissolve 2 drops (one at a time) slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor

Other information

- phenylketonurics: contains phenylalanine 1 mg per drop
- excessive consumption may have a laxative effect
- 5 calories per drop
- Contains: soy.

Inactive ingredients

acesulfame potassium, aspartame, eucalyptus oil, FDC blue 1, FDC red 40, flavors, isomalt, sodium carboxycellulose, soy lecithin, water

Questions

Call **1-800-524-2854**, Monday to Friday, 9AM-6PM Eastern Time or *visit our website at* www.gethalls.com

OTC Principal Display Panel

NDC 12546-107-50 Halls Sugar Free Black Cherry 50 Drops Bottle



HALLS SUGAR FREE BLACK CHERRY

menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-107
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10 EIP3A) (Menthol - UNII:L7T10 EIP3A)	Menthol	3.7 mg	

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)		
ASPARTAME (UNII: Z0H242BBR1)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
ISOMALT (UNII: S870P55O2W)		
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics				
Color	red (RED)	Score	no score	
Shape	OVAL	Size	18 mm	
Flavor	CHERRY (BLACK CHERRY)	Imprint Code	Н	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-107-50	50 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2011	

Labeler - Kraft Foods Global, Inc. (039010590)

Revised: 4/2011 Kraft Foods Global, Inc.