

HALLS CHERRY- menthol lozenge
Mondelēz Global 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.

Drug Facts

Active Ingredient

(in each drop) Menthol 7 mg

Purposes

Cough Suppressant, Oral Anesthetic

Uses

- 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 1 drop slowly in the mouth. Repeat every 2 hours as needed
- children under 5 years: ask a doctor

Other information

- 15 calories per drop
- **Contains: SOY**

Inactive ingredients

eucalyptus oil, FDC blue 2, FDC red 40, flavors, glucose syrup, soy lecithin, sucralose, sucrose, 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

Enter section text here NDC 12546-165-09 Halls Cherry 9 drops package



HALLS CHERRY

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-165
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	7 mg

Inactive Ingredients

Ingredient Name	Strength
Eucalyptus oil (UNII: 2R04ONI662)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
water (UNII: 059QF0KO0R)	

Product Characteristics

Color	red (red)	Score	no score
Shape	SQUARE	Size	21mm
Flavor	CHERRY (Cherry)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-165-09	09 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2013	

Labeler - Mondelēz Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelēz Canada Inc.		246791201	manufacture(12546-165)

Revised: 3/2013

Mondelēz Global LLC