

HALLS HONEY LEMON- menthol lozenge
Mondelez 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

(per drop) Menthol 8.8 mg

Purposes

<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

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

<beta carotene, eucalyptus oil, flavors, glucose syrup, honey, soy lecithin, sucralose, sucrose, water>

Questions

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

OTC Principal Display Panel

<NDC 12546-320-09 Halls Honey Lemon 9ct stick>

04050048358500 / ROLL-10111349



Drug Facts

Active ingredient (per drop) Menthol 2.5 mg

Purposes Cough suppressant, Oral anesthetic

Uses temporarily relieves: cough due to a cold occasional minor irritation or sore throat.

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Drug Facts (continued)

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: 90%.

Inactive ingredients beta carotene, eucalyptus oil, flavors, glucose syrup, honey, soy lecithin, sucralose, sucrose, water

Questions? Call 1-888-824-2884, Monday to Friday, 9 AM - 8 PM Eastern Time or visit our website at www.gethalls.com

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HALLS HONEY LEMON

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-320
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	8.8 mg

Inactive Ingredients

Ingredient Name	Strength
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
HONEY (UNII: Y9H1V576FH)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	yellow (yellow)	Score	no score
Shape	SQUARE	Size	20mm
Flavor	HONEY (HONEY LEMON)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-320-09	09 in 1 PACKAGE; Type 0: Not a Combination Product	03/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/24/2019	

Labeler - Mondelez Global LLC (050964956)**Establishment**

Name	Address	ID/FEI	Business Operations
Mondelēz Canada Inc		246791201	manufacture(12546-320)

Revised: 3/2019

Mondelez Global LLC