HALLS CHERRY- 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 6.8 mg>

Purposes

<Cough suppressant, Oral anesthetic>

Uses

<Temporarily relieves:</pre>

- cough due to a cold
- ocassional 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
- 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

<NDC 12546-333-09 Halls Cherry 9ct stick>



HALLS CHERRY

menthol lozenge

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:12546-333 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6.8 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, SO YBEAN (UNII: 1DI56 QDM62)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
SUCRO SE (UNII: C151H8 M554)				
WATER (UNII: 059QF0KO0R)				

Product Characteristics				
Color	red (Red)	Score	no score	
Shape	SQUARE	Size	21mm	
Flavor	CHERRY (Cherry)	Imprint Code	Н	
Contains				

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:12546-333-09	09 in 1 PACKAGE; Type 0: Not a Combination Product	03/13/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	11/21/2016		

Labeler - Mondelez Global LLC (050964956)

Establishment				
Name	Address	ID/FEI	Business Operations	
Mondelez Canada Inc		246791201	manufacture(12546-333)	

Revised: 3/2019 Mondelez Global LLC