

**HALLS MENTHO-LYPTUS- menthol lozenges**  
**Mondelez Global LLC**

-----  
**Halls menthol lozenge**

**Active Ingredient**

<(per drop) Menthol 5.4 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 by fever, headache, rash, swelling, 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**

Enter section text here

**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

- 10 calories per drop
- **Contains: SOY.**

## Inactive ingredients

<citric acid, eucalyptus oil, FDC blue 1, FDC red 40, flavors, glucose syrup, potassium citrate, soy lecithin, sucrose, water>

## Questions

<Call **1-800-524-2854**, Monday to Friday, 9AM-6PM Eastern Time or **visit our website at [www.gethalls.com](http://www.gethalls.com)**>

## OTC Principal Display Panel



## HALLS MENTHO-LYPTUS

menthol lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12546-112
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.4 mg

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CORN SYRUP</b> (UNII: 9G5L16BK6N)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	blue (LIGHT BLUE WTH BLUE SPECKS)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>	MENTHOL (MENTHO-LYPTUS)	<b>Imprint Code</b>	H
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-112-30	30 in 1 BAG; Type 0: Not a Combination Product	04/07/2019	
2	NDC:12546-112-14	14 in 1 BAG; Type 0: Not a Combination Product	09/01/2020	03/21/2023
3	NDC:12546-112-40	40 in 1 BAG; Type 0: Not a Combination Product	04/07/2019	08/21/2023
4	NDC:12546-112-80	80 in 1 BAG; Type 0: Not a Combination Product	04/07/2019	
5	NDC:12546-112-89	200 in 1 BAG; Type 0: Not a Combination Product	04/07/2019	
6	NDC:12546-112-96	96 in 1 BAG; Type 0: Not a Combination Product	04/07/2019	04/21/2020

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/07/2019	

**Labeler** - Mondelez Global LLC (091849786)

### Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc.		246791201	manufacture(12546-112)