

**HALLS STRAWBERRY- menthol lozenges**  
**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.*

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**Drug Facts**

**Active Ingredient**

<(per drop) Menthol 3.2 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**

Enter section text here

**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**

- 15 calories per drop

- **Contains: SOY.**

**Inactive ingredients**

<eucalyptus oil, 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**

<NDC 12546-219-09 Halls Strawberry 9ct stick>

04050048380800 / ROLL-10111349

NONIOL • COUGH SUPPRESSANTAL ANESTHETIC

# HALLS RELIEF

Relieves Coughs & Soothes Sore Throats  
Cools Nasal Passages

Strawberry Flavor

Cooling Flavor Meter ●●●○○○



9 DROPS

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**Drug Facts (continued)**

**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**      ■ 15 calories per drop      ■ Contains: 60Y.

**Inactive ingredients:** eucalyptus oil, FD&C red 40, flavors, glucose syrup, soy lecithin, sucralose, sucrose, water

**Questions?** Call 1-888-824-2884, Monday to Friday, 9 AM - 6 PM Eastern Time or visit our website at [www.gethalls.com](http://www.gethalls.com)

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## HALLS STRAWBERRY

menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-219
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Menthol</b> (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	3.2 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<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>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	red (red)	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	21mm
<b>Flavor</b>	STRAWBERRY (Strawberry)	<b>Imprint Code</b>	H
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-219-09	09 in 1 PACKAGE; Type 0: Not a Combination Product	06/16/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/16/2019	

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

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc.		246791201	manufacture(12546-219)

Revised: 6/2019

Mondelez Global LLC