

**HALLS APPLE CIDER- 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.*

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**Drug Facts**

**Active ingredient**

<(in each drop) Menthol 5.7 mg>

**Purposes**

<Cough suppressant, Oral anesthetic>

**Uses**

<temporarily relieves:>

- cough due to a cold
- occasional minor irritation or sore throat

**Warnings**

<Sore throat warnings: 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, caramel color, FDandC blue 1, FDandC red40, FDandC yellow 5 , flavors, glucose syrup, glycerin, malic acid, partially hydrogenated cottonseed oil, 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 12546-106-20 Halls Warm Ups Apple Cider 20 Drops Bag>





## HALLS APPLE CIDER

menthol lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12546-106
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Menthol</b> (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	5.7 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MALIC ACID</b> (UNII: 817L1N4CKP)	
<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>	brown (LIGHT BROWN)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>	APPLE (APPLE CIDER FLAVOR)	<b>Imprint Code</b>	H
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-106-20	20 in 1 BAG		
2	NDC:12546-106-02	2 in 1 BAG		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/23/2013	

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

Revised: 7/2013

Mondelez Global LLC