

**HALLS EXTRA STRONG MENTHOL MENTHOL- 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 Ingredients**

<(per drop) Menthol 20 mg>

**Purposes**

<Oral anesthetic>

**Uses**

<temporarily relieves occasional minor irritation and pain associated with:>

-sore throat

-sore mouth

**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.>

**Stop use and ask a doctor if**

- 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**

- 10 calories per drop

- **Contains: SOY.**

### **Inactive Ingredients**

<citric acid, eucalyptus oil, FD&C blue 1, flavors, glucose syrup, potassium citrate, 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](http://www.gethalls.com)>

### **OTC Principal Display Panel**

<NDC12546-341-30 Halls Extra Strong Menthol Flavor 30ct Bag>



**Extra Strong  
Menthol Flavor**  
Cooling Flavor Meter



**30  
DROPS**



**CHOKING WARNING**  
Not for children under 4.  
www.hallsdroplets.com

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MADE IN CANADA  
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04050050328487/BAG-10220649

**Questions?** Call 1-800-824-2864, Monday to Friday, 9 AM - 6 PM Eastern Time  
or visit our website at [www.gethalls.com](http://www.gethalls.com)

**Inactive ingredients:** citric acid, sucralose, FD&C blue 1, threonine, glucose syrup, potassium citrate, soy lecithin, sucrose, sorbitol, water

**Other information** ■ 10 calories per drop ■ Contains: SOY.

**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.

**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.  
Stop use and ask a doctor if: ■ sore throat does not improve in 7 days ■ irritation, pain, or redness persists or worsens.  
Keep out of reach of children.

**Uses** Temporarily relieves occasional minor irritation and pain associated with:  
■ sore throat ■ sore mouth

**Drug Facts**  
**Active ingredient (per drop)** Menthol 20 mg  
**Purpose** Oral anesthetic

Helps Support the  
Immune System



Soothes Everyday  
Irritation



Relieves Coughs  
Sore Throats



The right HALLS for the right moment.

# HALLS EXTRA STRONG MENTHOL MENTHOL

menthol lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12546-341
<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	20 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	white (White with blue specks)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>	MENTHOL (Extra Strong Menthol)	<b>Imprint Code</b>	H
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-341-30	30 in 1 BAG; Type 0: Not a Combination Product	07/26/2019	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	07/26/2019	

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

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Mondelez Canada Inc.		246791201	manufacture(12546-341)

Revised: 5/2021

Mondelez Global LLC