

**HALLS BUTTERSCOTCH- 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 mg>

**Purposes**

<Cough Suppressant, Oral Anesthetic>

**Uses**

- 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 persist 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**

- 15 calories per drop
- **contains: soy**

## Inactive ingredients

<beta carotene, caramel color, flavors, glucose syrup, glycerin, partially hydrogenated cottonseed oil, soy lecithin, sucrose, water>

## Questions

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

## OTC Principal Display Panel

The image shows the principal display panel of a Halls Warm-Ups Butterscotch Flavor wax melt. The packaging is primarily orange and blue. At the top left, it says "FAST RELIEF" with a circular icon. Below that is the "HALLS" logo in a blue and white shield shape. Underneath is "Warm-Ups" in a large, white, cursive font. Below that, it says "MENTHOL = COUGH SUPPRESSANT/ORAL ANESTHETIC". The central image shows a wax melt being broken apart, with several other wax melts scattered around it. Below the image, it says "BUTTERSCOTCH FLAVOR". The main text on the panel reads "WARMING & COOLING" in large white letters, followed by three bullet points: "GENTLY WARMS AND SOOTHES THROAT" and "COOLS NASAL PASSAGES". At the bottom left is the "FreshLock" logo, and at the bottom right is "20 DROPS". The bottom section of the panel contains a barcode, a lot number "12546163037", and a list of ingredients and directions.

FAST RELIEF  
START WORKING AGAIN IN SECONDS

RESEALABLE WAX

**HALLS**

**Warm-Ups**

MENTHOL = COUGH SUPPRESSANT/ORAL ANESTHETIC

BUTTERSCOTCH FLAVOR

**WARMING & COOLING**

- ▲ GENTLY WARMS AND SOOTHES THROAT
- ▲ COOLS NASAL PASSAGES

FreshLock

20 DROPS

3 12546163037 6

DISTRIBUTED BY: MONDELEZ GLOBAL LLC  
EAST HANOVER, NJ 07936 USA  
MADE IN CANADA  
© Mondelez International Group  
FRESH LOCKED IN A RESEALABLE TRAYS/BOX OR POUCHES OF POUCHES COMPANY.  
0 40502 799200 / 4-1266

Keep out of reach of children.  
Stop now and seek a doctor if:  
● cough persists for more than 1 week, needs to rest, or accompanied by fever, rash, or other symptoms. There could be signs of a sinus condition.  
● sore throat does not improve in 7 days.  
● infection, ear, or redness persists or worsens.  
● pain or irritation occurs.  
● you are pregnant or breastfeeding.  
● you are taking any other medications.  
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**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, flavors, glucose syrup, glycerin, partially hydrogenated cottonseed oil, soy lecithin, sucrose, water.

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Enter section text here<USNDC 12546-108-20 and CA NDC 67238-108-20 Halls Warm Ups Butterscotch 20 drops bag>

## HALLS BUTTERSCOTCH

menthol lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12546-108
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	5 mg

### Inactive Ingredients

Ingredient Name	Strength
BETA CAROTENE (UNII: 01YAE03M7J)	
CARAMEL (UNII: T9D99G2B1R)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>	bro wn (LIGHT BROWN)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>	BUTTERSCOTCH (BUTTERSCOTCH FLAVOR)	<b>Imprint Code</b>	H
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-108-20	20 in 1 BAG		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/01/2011	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc		246791201	manufacture(12546-108)

Revised: 7/2013

Mondelez Global LLC