## HALLS MOCHA MINT- 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

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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**

<caramel color, FDC blue 1, FDC red 40, FDC yellow 5 (tartrazine), 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>

## **OTC Principal Display Panel**

<NDC 12546-105-20 Halls Warm Ups Mocha Mint 20 drops bag>





## HALLS MOCHA MINT

menthol lozenge

## **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-105
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Route of Administration 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
CARAMEL (UNII: T9D99G2B1R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SO YBEAN (UNII: 1DI56 Q DM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

## **Product Characteristics**

Color	brown (LIGHT BROWN)	Score	no score
Shape	OVAL	Size	22mm
Flavor	MINT (MOCHA MINT FLAVOR)	Imprint Code	Н
Contains			

## Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:12546-105-20	20 in 1 BAG		
2 NDC:12546-105-02	2 in 1 BAG		

## **Marketing Information**

OTC monograph final	part341	10/01/2013

# Labeler - Mondelez Global LLC (050964956)

Establishment				
Name	Address	ID/FEI	Business Operations	
Mondelez Canada Inc.		246791201	manufacture(12546-105)	

Revised: 8/2013 Mondelez Global LLC