

**HALLS HONEY LEMON- 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.*

-----  
**HALLS HONEY LEMON bag**

**Active ingredient**

<(per drop) Menthol 7.5 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 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**

<beta carotene, eucalyptus oil, flavors, glucose syrup, honey, soy lecithin, sucralose, sucrose, water>

**Questions**

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

**OTC Principal Display Panel**



<b>HALLS HONEY LEMON</b>			
menthol lozenge			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12546-110
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	7.5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>.BETA.-CAROTENE</b> (UNII: 01YAE03M7J)	

## Product Characteristics

<b>Color</b>	yellow (yellow)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>	HONEY (HONEY LEMON)	<b>Imprint Code</b>	H
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-110-18	18 in 1 BAG; Type 0: Not a Combination Product	03/24/2019	09/16/2022
2	NDC:12546-110-30	30 in 1 BAG; Type 0: Not a Combination Product	03/24/2019	
3	NDC:12546-110-24	24 in 1 BAG; Type 0: Not a Combination Product	12/02/2019	06/11/2023
4	NDC:12546-110-40	40 in 1 BAG; Type 0: Not a Combination Product	03/24/2019	07/22/2023
5	NDC:12546-110-80	80 in 1 BAG; Type 0: Not a Combination Product	03/24/2019	
6	NDC:12546-110-16	16 in 1 BAG; Type 0: Not a Combination Product	03/24/2019	09/16/2022
7	NDC:12546-110-96	96 in 1 BAG; Type 0: Not a Combination Product	03/24/2019	04/21/2020
8	NDC:12546-110-14	14 in 1 PACKAGE; Type 0: Not a Combination Product	03/24/2019	
9	NDC:12546-110-99	160 in 1 BAG; Type 0: Not a Combination Product	03/24/2019	
10	NDC:12546-110-02	150000 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	12/02/2019	09/16/2022
11	NDC:12546-110-03	2400 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	12/02/2019	09/16/2022
12	NDC:12546-110-04	720 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	12/02/2019	09/16/2022
13	NDC:12546-110-00	250 in 1 JAR; Type 0: Not a Combination Product	07/06/2022	
14	NDC:12546-110-01	140 in 1 BAG; Type 0: Not a Combination Product	04/10/2023	

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
OTC monograph final	M012	03/24/2019	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc.		246791201	manufacture(12546-110)

Revised: 7/2023

Mondelez Global LLC