

HALLS HONEY VANILLA- 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 Vanilla

Active Ingredient

<(per drop) Menthol 2.5 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 by fever, headache, rash, swelling, 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 2 drops (one at a time) 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, flavors, glucose syrup, honey, 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>

OTC Principal Display Panel



HALLS HONEY VANILLA			
menthol lozenge			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-338
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 mg	
Inactive Ingredients			
Ingredient Name	Strength		

.BETA.-CAROTENE (UNII: 01YAE03M7J)	
HONEY (UNII: Y9H1V576FH)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	21mm
Flavor	HONEY (Honey Vanilla)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-338-30	30 in 1 BAG; Type 0: Not a Combination Product	03/05/2019	
2	NDC:12546-338-80	80 in 1 BAG; Type 0: Not a Combination Product	03/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/05/2019	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc		246791201	manufacture(12546-338)

Revised: 3/2023

Mondelez Global LLC