

HALLS HONEY- 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.

Drug Facts

Active Ingredient

<(per drop) Menthol 1.8 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.

Directions

- <adults and children 5 years and over: dissolve 3 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

<FD&C blue 1, FD&C red 40, FD&C yellow 5 (tartrazine), flavors, glucose syrup, honey, 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

<Halls Honey 30 Drop Bag 12546-241-30>

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-241
Route of Administration	Oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	menthol	1.8 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HONEY (UNII: Y9H1V576FH)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-241-30	30 in 1 BAG; Type 0: Not a Combination Product	01/25/2019	
2	NDC:12546-241-40	40 in 1 BAG; Type 0: Not a Combination Product	01/25/2019	
3	NDC:12546-241-80	80 in 1 BAG; Type 0: Not a Combination Product	01/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/25/2019	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2019

Mondelez Global LLC