HALLS SUGAR FREE MOUNTAIN MENTHOL- menthol lozenge Mondelez Global LLC

HALLS Sugar Free Mountain Menthol

Active Ingredient

<(per drop) Menthol 5.8 mg>

Purposes

<Cough Suppressant, Oral Anesthetic>

Uses

<temporarily relieves:</pre>

- cough due to a cold
- occasional minor irritation or sore throat>

Warnings

<Sore throat warnings: if sore throat is severe, persist 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

- phenylketonurics: contains phenylalanine 2 mg per drop
- excessive consumption may have a laxative effect
- 5 calories per drop
- contains: SOY.

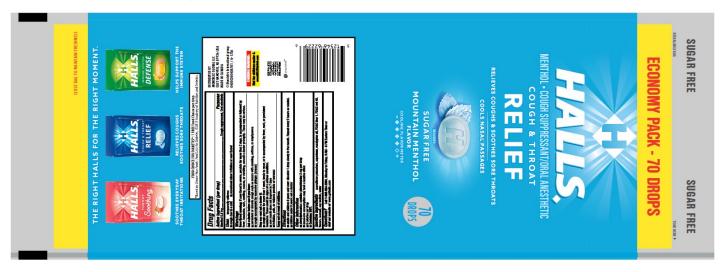
Inactive ingredients

<acesulfame potassium, aspartame, eucalyptus oil, FDC Blue 1, FDC Red 40, flavors, isomalt, sodium carboxymethylcellulose, soy lecithin, 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 SUGAR FREE MOUNTAIN MENTHOL

menthol lozenge

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-640	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.8 mg

Inactive Ingredients				
Ingredient Name	Strength			
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)				
ASPARTAME (UNII: Z0H242BBR1)				
EUCALYPTUS OIL (UNII: 2R040NI662)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
ISOMALT (UNII: S870P55O2W)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
WATER (UNII: 059QF0KO0R)				

Product Characteristics			
Color	blue (light blue)	Score	no score
Shape	OVAL	Size	21mm
Flavor	MENTHOL (MOUNTAIN MENTHOL)	Imprint Code	Н
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:12546-640- 25	25 in 1 BAG; Type 0: Not a Combination Product	06/03/2019	06/21/2024	
2	NDC:12546-640- 70	70 in 1 BAG; Type 0: Not a Combination Product	06/03/2019		
3	NDC:12546-640- 99	250 in 1 JAR; Type 0: Not a Combination Product	09/02/2024		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/03/2019	

Labeler - Mondelez Global LLC (091849786)

Establishment					
Name	Address	ID/FEI	Business Operations		
Mondelez Canada Inc.		246791201	manufacture(12546-640)		

Revised: 12/2023 Mondelez Global LLC