

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:

- 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.

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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

- 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: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ISOMALT (UNII: S870P55O2W)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
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	H
Contains			

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:12546-640-98	225 in 1 JAR; Type 0: Not a Combination Product	07/02/2024	
4	NDC:12546-640-01	150000 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	11/05/2024	

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)