HALLSSUGAR FREE EXTRA SUGAR FREE EXTRA STRONG MENTHOL-
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 Ingredients

<(in each drop) 18 mg>

Purposes

<Oral Anesthetic>

Uses

<temporarily relieves occasional minor irritation and pain associated with
- sore throat
- sore mouth>

Warnings

<Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headached, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.>

Stop Use and Ask a Doctor if
- 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 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, citric acid, eucalyptus oil, FDC blue 1, flavors, isomalt, sodium

carboxymethylcellulose, soy lecithin, 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 Sugar Free Extra Strong Menthol Flavor 9 drops package US NDC 12546-314-09 and CA NDC 67238-314-09>

HALLSSUGAR FREE EXTRA SUGAR FREE EXTRA STRONG MENTHOL

menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12546-314
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	18 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOMALT (UNII: S870P55O2W)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white (white with blue speckles)	**Score**	no score
Shape	SQUARE	**Size**	21mm
Flavor	MENTHOL (Sugar Free Extra Strong)	**Imprint Code**	H
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:12546-314-09	09 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/04/2014	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc.		246791201	manufacture(12546-314)

Revised: 2/2014 Mondelez Global LLC