HALLSSUGAR FREE EXTRA SUGAR FREE EXTRA STRONG MENTHOLmenthol 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: sov

Inactive ingredients

<acesulfame potassium, aspartame, citric acid, eucalyptus oil, FDC blue 1, flavors, isomalt, sodium

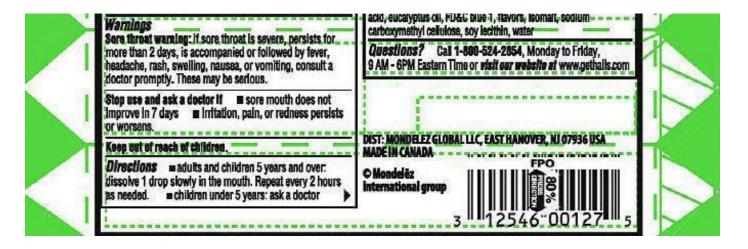
Questions

<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 TypeHUMAN OTC DRUGItem Code (Source)NDC:12546-314

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A) MENTHOL 18 mg

Inactive Ingredients Ingredient Name Strength ACESULFAME POTASSIUM (UNII: 230 V73Q5G9) ASPARTAME (UNII: Z0 H242BBR1) CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8QP) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) ISOMALT (UNII: S870 P550 2W) CARBO XYMETHYL CELLULO SE SODIUM (UNII: K679 OBS 311) LECITHIN, SO YBEAN (UNII: 1D156 QDM62) WATER (UNII: 059 QF0 K00R)

Product Characteristics					
Color	white (white with blue speckles)	Score	no score		
Shape	SQUARE	Size	21mm		
Flavor	MENTHOL (Sugar Free Extra Strong)	Imprint Code	Н		
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	0 2/0 4/20 14						

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