HALLS PLUS STRAWBERRY- 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

<(in each drop) Menthol 2.7 mg>

Purposes

<Cough Suppressant, Oral Anesthetic>

Uses

- 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 persist or worsens

Keep out of reach of children

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Directions

- adults and children 5 years and over: dissolve 2 drops (one at a time) slowly in the mouth. Repeat every 2 hours as needed
- children under 5 years: ask a doctor

Other information

- 15 calories per drop
- contains: soy

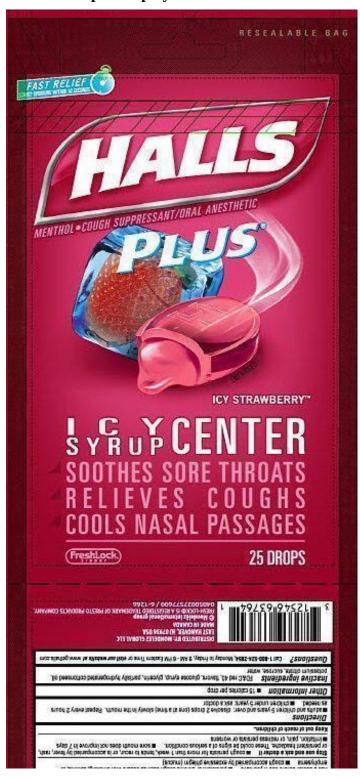
Inactive ingredients

<FDC red40, flavors, glucose syrup, glycerin, partially hydrogenated cottonseed oil, potassium citrate, 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





Enter section text here<USNDC 12546-985-25 and

CA NDC 67238-985-25 Halls Plus Icy Syrup Center Strawberry Flavor 25 drops bag>

HALLS PLUS STRAWBERRY

menthol lozenge

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:12546-985

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthal (UNII: L.7T10EIP3A) (Menthal - UNII:L.7T10EIP3A)	Menthol	2.7 mg

Inactive Ingredients

Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
POTASSIUM CITRATE (UNII: EE90ONI6FF)			
LECITHIN, SO YBEAN (UNII: 1DI56 Q DM62)			
SUCROSE (UNII: C151H8M554)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics

1 Todact Characteristics			
Color	red (Red)	Score	no score
Shape	OVAL	Size	22mm
Flavor	STRAWBERRY (Plus Strawberry)	Imprint Code	Н
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-985-25	25 in 1 BAG		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2013	

Labeler - Mondelez Global LLC (050964956)

Establishment				
Name	Address	ID/FEI	Business Operations	
Mondelez Canada Inc.		246791201	manufacture(12546-985)	

Revised: 7/2013 Mondelez Global LLC