

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

Enter section text here

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

The image shows the principal display panel of a Halls Plus Icy Strawberry Syrup Center. The packaging is primarily red with white and blue accents. At the top, it says 'RESEALABLE BAG'. A green banner at the top left reads 'FAST RELIEF' with a clock icon and 'Can be working within 15 seconds'. The brand name 'HALLS' is prominently displayed in white on a red background. Below it, 'MENTHOL • COUGH SUPPRESSANT/ORAL ANESTHETIC' is written in white. The word 'PLUS' is in large, blue, 3D letters. Below 'PLUS' is an illustration of a clear plastic bottle of syrup and a red, round, textured lozenge. The flavor 'ICY STRAWBERRY™' is written in white. The product name 'ICY SYRUP CENTER' is in large, white, bold letters. Below that, three benefits are listed: 'SOOTHES SORE THROATS', 'RELIEVES COUGHS', and 'COOLS NASAL PASSAGES'. At the bottom left is the 'FreshLock' logo, and at the bottom right is '25 DROPS'. The bottom section of the panel contains a barcode, a lot number '1254663764', and various regulatory and contact information.

RESEALABLE BAG

FAST RELIEF
Can be working within 15 seconds

HALLS

MENTHOL • COUGH SUPPRESSANT/ORAL ANESTHETIC

PLUS

ICY STRAWBERRY™

ICY SYRUP CENTER

SOOTHES SORE THROATS
RELIEVES COUGHS
COOLS NASAL PASSAGES

FreshLock

25 DROPS

1254663764

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EAST MANHETEN, NY 07030 USA
MADE IN CANADA
0400002757100 / 0.1716g

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 lozenges per drop.

Inactive ingredients FDC red 40, flavor, glucose syrup, glycerin, partially hydrogenated cottonseed oil, potassium citrate, 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

Keep out of reach of children.
Stop use and ask a doctor if ■ cough persists for more than 7 days, ■ sore throat does not improve in 7 days, ■ hoarseness, pain, or redness persists or worsens.
■ sore mouth does not improve in 7 days.

■ cough accompanied by excessive phlegm (mucus)



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 Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-985
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	2.7 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	red (Red)	Score	no score
Shape	OVAL	Size	22mm
Flavor	STRAWBERRY (Plus Strawberry)	Imprint Code	H
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