

HALLS KIDS 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

<(per pop) Menthol 5 mg>

Purposes

<Cough Suppressant, Oral Anesthetic>

Uses

<temporarily relieves:>

- 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 by fever, headache, rash, swelling, 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

Directions

- adults and children 5 years and over: dissolve 1 pop slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor

Other information

- 25 calories per pop

Inactive ingredients

<citric acid, FD&C red 40, flavors, glucose syrup, potassium citrate, sucrose, 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

<NDC 12546-337-10 Halls Kids Strawberry 10ct Bag>



HALLS KIDS

SORE THROAT & COUGH

Effective relief for coughs and sore throats

Pleasant cooling flavor

A fruity taste your child will enjoy



Try both flavors: **Cherry & Strawberry**

Drug Facts

Active Ingredient (per pop)

Menthol 5 mg

Purposes: Cough suppressant, Oral anesthetic

Uses

temporarily relieves: 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

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.

Keep out of reach of children. In children under 5 years and over: dissolve 1 pop slowly in the mouth. Repeat every 2 hours as needed. In children under 5 years: ask a doctor.

Directions

In adults and children 5 years and over: dissolve 1 pop slowly in the mouth. Repeat every 2 hours as needed. In children under 5 years: ask a doctor.

Other Information

25 calories per pop

Inactive Ingredients

citric acid, FD&C red 40, flavors, glucose syrup, potassium citrate, sucrose, water

Questions?

Call 1-800-824-2884, Monday to Friday, 9 AM - 6 PM Eastern Time or visit our website at www.gdtb.com

DISTRIBUTED BY

MONDELEZ GLOBAL LLC

EAST HANOVER, NJ 07936 USA

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BAG-10307355

CHOKING WARNING:

Not for children under 4.
www.MDL2KidsSafe.com



HALLS KIDS STRAWBERRY

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-337
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	20mm
Flavor	STRAWBERRY	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-337-10	10 in 1 BAG; Type 0: Not a Combination Product	07/26/2019	
2	NDC:12546-337-11	10 in 1 CARTON; Type 0: Not a Combination Product	08/05/2019	
3	NDC:12546-337-01	1 in 1 BAG; Type 0: Not a Combination Product	07/26/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/26/2019	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
BestCo Inc.		002149136	manufacture(12546-337)

Revised: 8/2019

Mondelez Global LLC