HALLS KIDS CHERRY- 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 blue 1, 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 12546-336-10 Halls Kids cherry Bag 10 ct>





www.MDLZKidsSafe.com Not for children under 4. CHOKING WARNING:

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Call 1-868-824-2364, Monday to Friday, 9 AM - 6 PM Eastern Time or

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Active ingredient (per pop)
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A fruity taste your child will

Pleasant cooling flavor

Effective relief for coughs and sore throats

SORE THROAT & COUGH







HALLS KIDS CHERRY

menthol lozenge

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:12546-336

Route of Administration ORAL

Active Ingredient/Active Moiety

2017 0 2138 2 0 112 112 112 112 112 112 112 112 112		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	5 mg

Inactive Ingredients Ingredient Name Strength ANHYDRO US CITRIC ACID (UNII: XF417D3PSL) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 40 (UNII: WZB9127XOA) POTASSIUM CITRATE (UNII: EE90ONI6FF) SUCRO SE (UNII: C151H8 M554) WATER (UNII: 059QF0KOOR)

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	20 mm
Flavor	CHERRY	Imprint Code	Н
Contains			

]	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-336-10	10 in 1 BAG; Type 0: Not a Combination Product	07/26/2019	
2	NDC:12546-336-11	10 in 1 CARTON; Type 0: Not a Combination Product	08/05/2019	
3	NDC:12546-336-01	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(12546-336)

Revised: 8/2019 Mondelez Global LLC