

HALLS KIDS HONEY APPLE- 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.

HALLS Kids Honey Apple

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

flavors, glucose syrup, honey, 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 12546-350-10 Halls Kids Honey Apple Bag 10 ct>





CHOKING WARNING:
No for children under 4.
www.MDLZKidsSafe.com

65 668
© No n d e z i n f e m a d a n a l g r a u p
EAS THAN OVER, N.J. 07936 USA
DISTR BU TE DB YMO ND EL EZ GL O BAL LLC

Drug Facts	
Active ingredient (per pop)	Menthol 5 mg
Purposes	Cough suppressant, Oral anesthetic
Uses	temporarily relieve:
Warnings	
Do not use if you have:	
- a fever, sore throat, or other cough such as occurs with smoking, asthma, or emphysema	
- a cough accompanied by excessive phlegm (mucus)	
- a cough that lasts 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.	
- a sore throat that does not improve in 7 days	
- irritation, pain, or redness persists or worsens	
Keep out of reach of children.	
Directions	
Use as directed. For children 5 years and over: dissolve 1 pop slowly in the mouth. Repeat every 2 hours as needed.	
Other information	
25 calories per pop	
Inactive ingredients	
flavor, glucose syrup, honey, sucrose, water	
Questions? call 1-800-424-2844, Monday to Friday, 9 AM - 6 PM Eastern Time or visit our website at www.guthrie.com	

Try flavors: Cherry & Strawberry



- ✓ Pleasant cooling flavor
- ✓ A kid-friendly flavor your child will enjoy
- ✓ and sore throats



HALLS KIDS HONEY APPLE

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-350
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
SUCROSE (UNII: C151H8M554)	
HONEY (UNII: Y9H1V576FH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow (pale yellow)	Score	no score
Shape	ROUND	Size	20mm
Flavor	HONEY (Honey Apple)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-350-10	10 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:12546-350-11	10 in 1 CARTON; Type 0: Not a Combination Product	03/30/2020	
3	NDC:12546-350-01	800 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	05/25/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/30/2020	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
BestCo Inc.		002149136	manufacture(12546-350)

Revised: 11/2021

Mondelez Global LLC