

HALLS SUGAR FREE WATERMELON- 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 Minis Sugar Free Watermelon

Active Ingredient

(per drop) Menthol 2.5 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, persist 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 persists or worsens

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

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

- phenylketonurics: contains phenylalanine 0.5 mg per drop
- excessive consumption may have a laxative effect
- <5 calories per drop
- **Contains: SOY.**

Inactive ingredients

acesulfame potassium, aspartame, citric acid, eucalyptus oil, FD&C red 40, flavors (includes cinnamon), isomalt, soy lecithin, water

Questions

Call 1-800-524-2854, Monday to Friday, 9 AM-6PM Eastern Time or visit our website at www.gethalls.com

OTC Principal Display Panel

<NDC 12546-351-24 Halls Sugar Free Watermelon 24ct>



SUGAR FREE

PULL DOWN

HALLS
MINIS

WATERMELON FLAVOR



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Other information

- **phenylethanamine:** contains phenylethanamine 0.5 mg per drop
- **excessive consumption may have a laxative effect**
- 45 calories per drop
- Contains 307.

Inactive ingredients: acetaminophen, aspirin, citric acid, saccharin, FD&C Red No. 40, Iron Oxide (black), titanium dioxide, water

Questions? Call 1-800-824-2264, Monday to Friday, 9 AM - 6 PM Eastern Time or visit our website at www.gfhalts.com

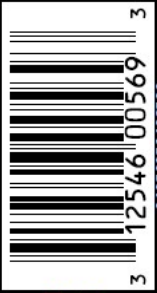
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MADE IN CANADA

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



HALLS SUGAR FREE WATERMELON

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-351
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ISOMALT (UNII: S870P55O2W)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	9mm
Flavor	WATERMELON	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-351-24	24 in 1 PACKAGE; Type 0: Not a Combination Product	12/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/13/2021	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
MSI Express, Inc		117973852	pack(12546-351)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc		246791201	manufacture(12546-351)

Revised: 12/2021

Mondelez Global LLC