

HALLS SUGAR FREE MENTHO-LYPTUS- 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 mentho-lyptus 24ct

Active ingredient

<(per drop) Menthol 2.7 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

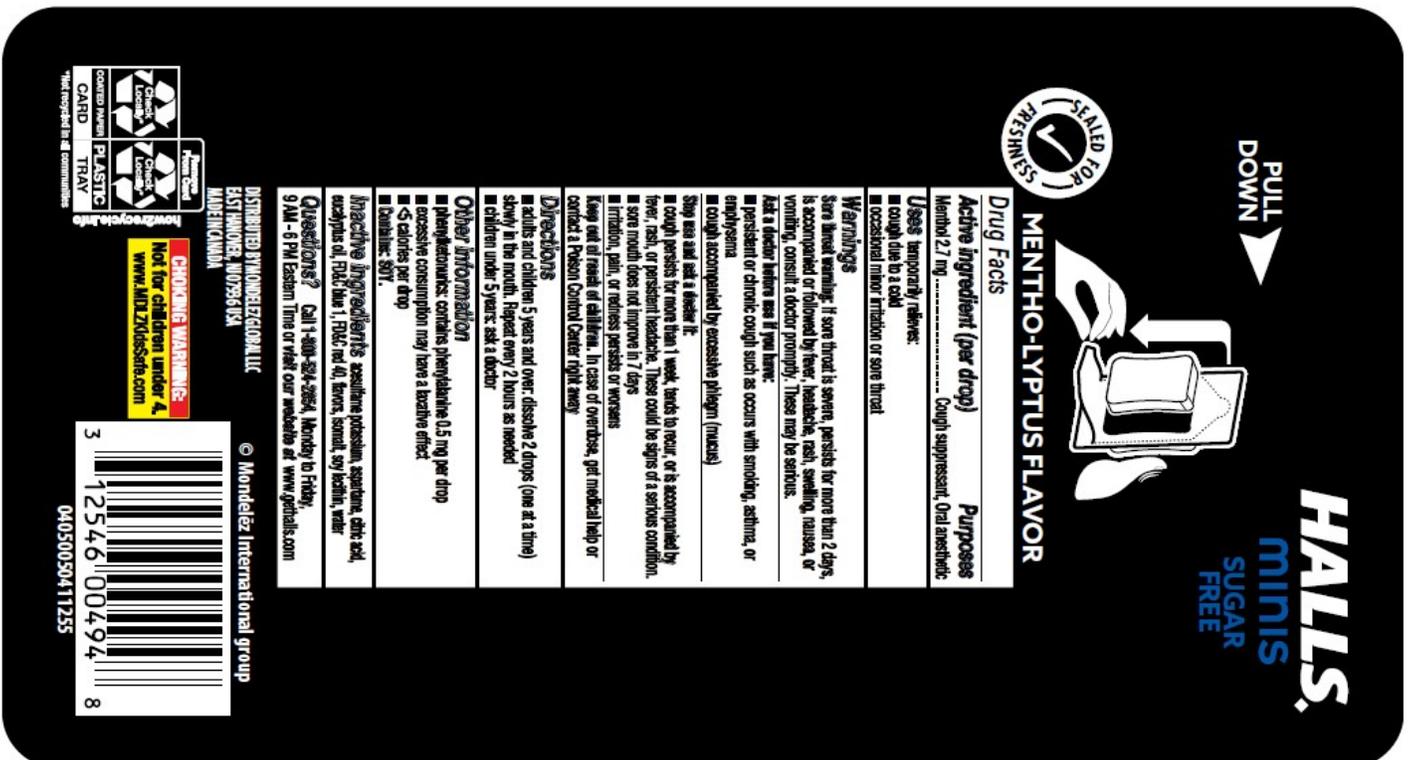
<acesulfame potassium, aspartame, citric acid, eucalyptus oil, FD&C blue 1, FD&C red 40, flavors, isomalt, soy lecithin, water>

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





HALLS SUGAR FREE MENTHO-LYPTUS

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-349
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
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ISOMALT (UNII: S870P55O2W)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	9mm
Flavor	MENTHOL (Mentho-Lyptus)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-349-03	11667 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	10/21/2020	10/03/2022
2	NDC:12546-349-24	24 in 1 PACKAGE; Type 0: Not a Combination Product	10/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/21/2020	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
MSI Express Inc		117942991	pack(12546-349)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc		246791201	manufacture(12546-349)

Revised: 10/2022

Mondelez Global LLC