HALLS EXTRA STRONG MENTHOL MENTHOL- 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 Ingredients

<(per drop) Menthol 20 mg>

Purposes

<Oral anesthetic>

Uses

- <temporarily relieves occasional minor irritation and pain associated with:>
- -sore throat
- -sore mouth

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.>

Stop use and ask a doctor if

- 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 drop slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor

Other Information

• 10 calories per drop

Contains: SOY.

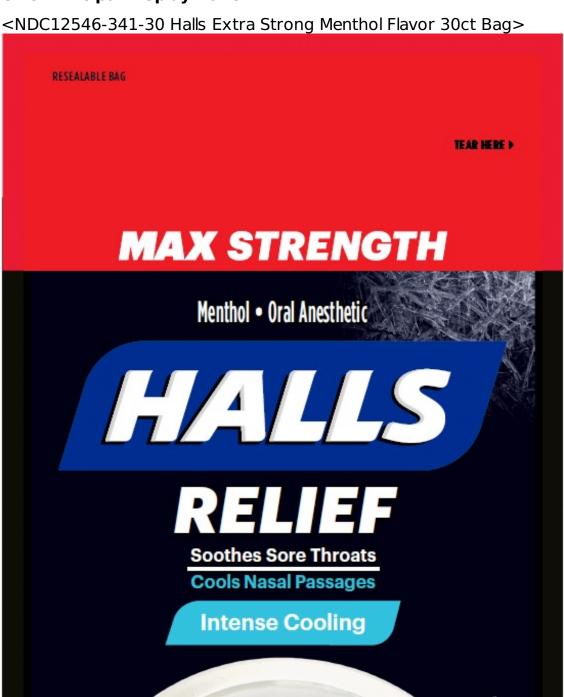
Inactive Ingredients

<citric acid, eucalyptus oil, FD&C blue 1, flavors, glucose syrup, potassium citrate, soy lecithin, sucralose, 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



The right HALLS for the right moment.







Helps Supportthe Immune System Soothes Everyday Throatlitteallons Relieves Coughs Soothes Sore Throats

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Extra Strong
Menthol Flavor
Collin Flavor
Collin Flavor

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HALLS EXTRA STRONG MENTHOL MENTHOL

menthol lozenge

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-341	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	20 mg	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
EUCALYPTUS OIL (UNII: 2R040NI662)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
POTASSIUM CITRATE (UNII: EE90ONI6FF)			
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SUCROSE (UNII: C151H8M554)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	white (White with blue specks)	Score	no score
Shape	OVAL	Size	21mm
Flavor	MENTHOL (Extra Strong Menthol)	Imprint Code	Н
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:12546-341- 30	30 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 not final	part356	07/26/2019	

Labeler - Mondelez Global LLC (050964956)

Establishment				
Name	Address	ID/FEI	Business Operations	
Mondelez Canada Inc.		246791201	manufacture(12546-341)	

Revised: 5/2021 Mondelez Global LLC