

HALLS BREEZERS SUGAR FREE COOL BERRY- pectin 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 sugar free Cool Berry

Active Ingredient

(per drop) Pectin 7 mg

Purpose

<Oral Demulcent>

Uses

<temporarily relieves the following symptoms associated with sore mouth and sore throat:

- minor discomfort
- irritated areas>

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 or 2 drops (one at a time) slowly in the mouth. Repeat as needed.
- children under 5 years: ask a doctor

Other information

- phenylketonurics: contains phenylalanine 2 mg per drop
- excessive consumption may have a laxative effect
- 10 calories per drop
- **Contains: SOY.**

Inactive ingredients

acesulfame potassium, aspartame, citric acid, FDC blue 2, FDC red 40, flavors, isomalt, malic acid, maltitol syrup, potassium citrate, soy lecithin, titanium dioxide, 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 BREEZERS SUGAR FREE COOL BERRY

pectin lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-720
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PECTIN (UNII: 89NA02M4RX) (PECTIN - UNII:89NA02M4RX)	PECTIN	7 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ISOMALT (UNII: S870P55O2W)	
MALIC ACID (UNII: 817L1N4CKP)	
MALTITOL (UNII: D65DG142WK)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red (red and white)	Score	no score
Shape	OVAL	Size	21mm
Flavor	BERRY (Cool Berry)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-720-20	20 in 1 BAG; Type 0: Not a Combination Product	05/27/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/27/2019	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc		246791201	manufacture(12546-720)