

BREEZERS CREAMY STRAWBERRY- pectin lozenges
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 Breezers creamy strawberry

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

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

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

- <•15 calories
- Contains: SOY.>

Inactive ingredients

<beta carotene, citric acid, FDC blue 2, FDC red 40, flavors, glucose syrup, lactic acid, malic acid, potassium citrate, sodium chloride, soy lecithin, sucrose, titanium dioxide, water>

Questions

<Call 1-800-524-2854, Monday to Friday, 9AM-5PM Eastern Time or visit our website at www.gethalls.com>

OTC Principal Display Panel

BREEZERS CREAMY STRAWBERRY

pectin lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-352
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
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LACTIC ACID (UNII: 33X04XA5AT)	
MALIC ACID (UNII: 817L1N4CKP)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (White with red stripe)	Score	no score
Shape	OVAL	Size	22mm
Flavor	STRAWBERRY (Creamy Strawberry)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-352-25	25 in 1 BAG; Type 0: Not a Combination Product	03/13/2019	
2	NDC:12546-352-30	30 in 1 BAG; Type 0: Not a Combination Product	03/13/2019	09/16/2022
3	NDC:12546-352-70	70 in 1 BAG; Type 0: Not a Combination Product	05/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/03/2016	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc		246791201	manufacture(12546-352)