

**BREEZERS TROPICAL CHILL- 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.*

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**Drug Facts**

**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**

- 15 calories per drop
- Contains: SOY.**

**Inactive ingredients**

<beta carotene, citric acid, FDC red 40, FDC yellow 5 (tartrazine), FDC yellow 6, flavors, glucose

syrup, malic acid, potassium citrate, soy lecithin, sucrose, titanium dioxide, water>

## Questions

<Call 1-800-524-2854, Monday to Friday, 9AM-6PM Eastern Time or visit our website at [www.gethalls.com](http://www.gethalls.com)>

## OTC Principal Display Panel

<NDC 12546-150-25 Halls Breezers Tropical Chill 25ct Bag>

RESEALABLE BAG

TEAR HERE

PECTIN • ORAL DEMULCENT

# HALLS

## BREEZERS

- Soothes Everyday Throat Irritations
- Great Taste

ENLARGED

COOLING FLAVOR METER

TROPICAL CHILL  
FLAVOR

25 DROPS

# FIND YOUR LEVEL OF COOL!

Let the Cooling Flavor Meter guide you.

[gethalls.com](http://gethalls.com)



## Drug Facts

**Active ingredient (per drop)**

**Purpose**

Temporarily relieves the following symptoms associated with sore mouth and sore throat: minor discomfort in 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

Keep out of reach of children.

## Directions

In adults and children 5 years and over: dissolve 1 or 2 drops (one at a time) slowly in the mouth. Repeat as needed. In children under 5 years: ask a doctor

## Other information

Contains 207. In 15 calories per drop

## Inactive ingredients

beta carotene, citric acid, FD&C red 40, FD&C yellow 5 (tartrazine), FD&C yellow 6, flavors, glucose syrup, male acid, potassium citrate, soy lecithin, sucrose, titanium dioxide, water

## Questions?

Call 1-800-824-2884, Monday to Friday, 9 AM - 8 PM Eastern Time or visit our website at [www.gethalls.com](http://www.gethalls.com)



**CHOKING WARNING:**  
**Not for children under 4.**  
[www.HALLSgethalls.com](http://www.HALLSgethalls.com)

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# BREEZERS TROPICAL CHILL

pectin lozenge

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-150
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 RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALIC ACID (UNII: 817L1N4CKP)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

Color	red (red with white stripe)	Score	no score
Shape	OVAL	Size	22mm
Flavor	FRUIT (Tropical Chill)	Imprint Code	H
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-150-25	25 in 1 BAG; Type 0: Not a Combination Product	11/21/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/21/2016	

Labeler - Mondelez Global LLC (050964956)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Mondelez Canada Inc		246791201	manufacture(12546-150)

Revised: 11/2016

Mondelez Global LLC