

**HONIBE - menthol lozenge**  
**Island Abbey Foods Ltd.**

*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**

MENTHOL

KEEP OUT OF REACH OF CHILDREN

TEMPORARILY RELIEVES:

COUGH DUE TO COLD

OCCASIONAL MINOR IRRITATION OR SORE THROAT

ORAL LOZENGE

HONEY, EUCALYPTUS OIL

ADULTS AND CHILDREN 5 YEARS AND OVER:

DISSOLVE 1 DROP SLOWLY IN MOUTH. REPEAT EVERY 2 HOURS AS NEEDED.

CHILDREN UNDER 5 CONSULT YOUR DOCTOR.

Enter section text here

IF SORE THROAT IS SEVERE, PERSIST FOR MORE THAN 2 DAYS OR IS ACCOMPANIED OR FOLLOWED BY FEVER HEADACHE,RASH,SWELLING,NAUSEA,VOMITING, CONSULT A DOCTOR PROMPTLY.

THESE SYMPTOMS MAY BE SERIOUS.



F R O N T

HBE3631

Enter section text here

## HONIBE

menthol lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50788-001
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8.6 mg in 2.5 g

### Inactive Ingredients

Ingredient Name	Strength
HONEY (UNII: Y9H1V576FH)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

## Product Characteristics

<b>Color</b>	yellow (honey yellow)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Lozenge)	<b>Size</b>	16 mm
<b>Flavor</b>	LEMON (LEMON OIL)	<b>Imprint Code</b>	raised;flower
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50788-001-02	1 in 1 BAG		
1	NDC:50788-001-01	25 g in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/30/2012	

**Labeler** - Island Abbey Foods Ltd. (243869661)

## Establishment

Name	Address	ID/FEI	Business Operations
Island Abbey Foods Ltd.		243869661	manufacture

Revised: 6/2012

Island Abbey Foods Ltd.