

HERBON GLACIAL MINT- echinacea purpurea, menthol, and eucalyptus oil lozenge
Purity Life Division of SunOpta

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.

INDICATIONS AND USAGE

Recommended Use: For the temporary relief of cough and sore throat pain. Helps relieve nasal congestion and make nasal passages feel clearer. Helps shorten the duration and relieve symptoms of the common cold.

Recommended Dose:

Adolescents (10 to 14 years): Dissolve 1 lozenge slowly in the mouth three times daily or more as needed.

Adults and adolescents (14 years and older): Dissolve 1 lozenge slowly in the mouth six times daily or more as needed.

Note: Do not exceed 14 lozenges per day. Consult a health care practitioner for use beyond eight weeks.

Medicinal Ingredients:

Each lozenge contains:

Echinacea (<i>Echinacea purpurea</i>) root extract 22:1 (equivalent to 162 mg dried herb)	7.35 mg
Menthol (from <i>Mentha arvensis</i> leaf)	10 mg
Eucalyptus oil (<i>Eucalyptus globulus</i>)	6 mg

Non-medicinal Ingredients: Natural flavours (lemon, wintermint), natural colours (alfalfa, carmine, curcumin), corn syrup, sugar.

Risk Information: Consult a health care practitioner if symptoms persist or worsen, if sore throat symptoms are severe or persist for more than two days, if cough worsens, persists for more than seven days or is accompanied by high fever. Consult a health care practitioner prior to use if you take immunosuppressants or have a progressive systemic disease such as tuberculosis, leukosis, collagenosis or multiple sclerosis.

DO NOT USE IF BAG IS OPEN OR TORN.

STORE IN A COOL, DRY PLACE.

KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL - 20 Lozenge Bag

Herbon®

ECHINACEA Cough and Sore Throat Drops

Original

Temporary Relief of
Cough & Sore Throat
Helps Ease Nasal Congestion

ALL NATURALLY-SOURCED
ACTIVE INGREDIENTS

Extra Strength

GLACIAL MINT

REFRESHING

BURSTS

of LEMON and
WINTERMINT

20 Lozenges



HERBON GLACIAL MINT
echinacea purpurea, menthol, and eucalyptus oil lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44597-5505
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Echinacea Purpurea (UNII: QI7G114Y98) (Echinacea - UNII:4N9P6CC1DX)	Echinacea	7.35 mg
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	10 mg
Eucalyptus Oil (UNII: 2R04ONI662) (Eucalyptus Oil - UNII:2R04ONI662)	Eucalyptus Oil	6 mg

Inactive Ingredients

Ingredient Name	Strength
Sucrose (UNII: C151H8M554)	2150.04 mg
Corn Syrup (UNII: 9G5L16BK6N)	

Product Characteristics

Color	YELLOW (Slightly opaque light yellowish green with deep pink and bright yellow speckles)	Score	no score
Shape	ROUND	Size	20mm
Flavor	LEMON (lemon, wintermint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44597-5505-1	12 in 1 CARTON		
1		20 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/30/2009	

Labeler - Purity Life Division of SunOpta (243105843)**Establishment**

Name	Address	ID/FEI	Business Operations
Purity Life Division of SunOpta		243105843	RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
F&F Laboratories Inc.		005092838	MANUFACTURE