

HERBON SUGAR FREE LEMON HONEY- menthol and echinacea purpurea lozenge
Purity Life Division of SunOpta Co.

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. Soothes throat irritation. 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 (*Echinacea purpurea*) root extract 22:1
(equivalent to 162 mg dried herb)7.35 mg
Menthol (from *Mentha arvensis* leaf)8 mg

Non-medicinal Ingredients: Natural flavours (honey lemon, lemon), natural colours (beta carotene, curcumin), citric acid, isomalt, xylitol.

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 - 18 Lozenge Bag

Herbon®

ECHINACEA Cough and Sore Throat Drops

Sugar-Free

*Temporary Relief of
Cough & Sore Throat
Helps Ease Nasal Congestion*

**ALL NATURALLY-SOURCED
ACTIVE INGREDIENTS**

LEMON HONEY

**REFRESHING
BURSTS
of LEMON**

18 Lozenges



HERBON SUGAR FREE LEMON HONEY

menthol and echinacea purpurea lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44597-5535
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	8 mg
Echinacea Purpurea (UNII: QI7G114Y98) (Echinacea - UNII:4N9P6CC1DX)	Echinacea	7.35 mg

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	16.93 mg
Xylitol (UNII: VCQ006KQ1E)	

Product Characteristics

Color	YELLOW (Translucent golden yellow with opaque yellow speckles)	Score	no score
Shape	ROUND	Size	20mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44597-5535-0	12 in 1 CARTON		
1		18 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 Co. (243105843)

Establishment

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

Establishment

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

Revised: 10/2009

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