# HERBION NATURALS HONEY LEMON - menthol lozenge Herbion Pakistan (Pvt.) 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.

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# **Drug Facts:**

# Active Ingredient (in each drop):

Menthol, 5.5mg

### **Purpose**

Menthol, 5.5mg.....Cough Suppressant / Oral Anesthetic

#### Uses

- temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
- for temporary relief of occasional minor irritation, pain, sore mouth and sore throat

# **Warnings**

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly. These may be serious.

#### Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that is accompanied by excessive phlegm (mucus)

#### Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition
- 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 2 years of age and over: Dissolve 1 drop slowly in mouth. Repeat every 2 hours as needed or as directed by a doctor
- children under 2 years of age: consult a physician

#### Other Information

- diabetic patients should not use Herbion drops without the advice of a physician and they should monitor glucose levels closely while taking drops as they may alter blood-glucose levels
- store in a cool, dry place, below 77°F
- protect from heat and light

# **Inactive Ingredients**

Ascorbic Acid, Artificial Honey Flavor, Artificial Lemon Flavor, Artificial Mint Flavor, Artificial Yellow Color, Artificial Brown Color, Cane Sugar, Citric Acid, Eucalyptus Oil, Greater Galangal Rhizome, Hyssop, Large-leaf Geiger Tree Fruit, Licorice Root, Liquid Glucose, Long Pepper Fruit, Malabar Nut Tree Leaf.

#### **Questions or Comments?**

1-888-(OK-HERBION) 654-3724, Monday through Friday, 9am - 5pm

#### **Side Panel**

Manufactured for: Herbion USA Inc. Williamsville, NY 14221 1-888-(OK-HERBION)-654-3724 Info.us@herbion.com www.herbion.com

Made in Pakistan

## **Principal Display Panel**

Principal Display Panel Herbion Naturals

Relieves Cough and Soothes Sore Throat

NATURAL CARE

cough drops

Menthol

-Cough Suppressant Honey Lemon -Oral Anesthetic 18 Drops



menthol lozenge

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:44237-300

Route of Administration ORAL

# Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.5 mg

Inactive Ingredients			
Ingredient Name	Strength		
SUCROSE (UNII: C151H8M554)			
DEXTROSE (UNII: IY9 XDZ35W2)			
ASCORBIC ACID (UNII: PQ6CK8PD0R)			
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)			
EUCALYPTUS OIL (UNII: 2R040NI662)			
JUSTICIA ADHATODA LEAF (UNII: HH159 XOV8 1)			
LONG PEPPER (UNII: 2NMG4EA7B1)			
CORDIA SEBESTENA FLOWER (UNII: LM8F18O4OJ)			
GREATER GALANGAL (UNII: 7Y64R856MB)			
HYSSOPUS OFFICINALIS WHOLE (UNII: 0 IQW0 0 1KPE)			
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)			

# Product Characteristics Color yellow, brown Score no score Shape ROUND Size 17mm Flavor HONEY, LEMON Imprint Code

Contains

# Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:44237-300-18 2 in 1 CARTON 9 in 1 BLISTER PACK

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/24/2013		

Establishment						
Name	Address	ID/FEI	Business Operations			
Herbion Pakistan (Pvt.) Ltd		645482936	manufacture(44237-300)			

Revised: 12/2013 Herbion Pakistan (Pvt.) Ltd