

## **HERBION NATURALS ORANGE COUGH DROPS- 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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### **Active ingredient (in each drop):**

Menthol, 5.5mg

### **Purpose:**

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

### **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, Natural flavor, 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 - 5am







# HERBION NATURALS ORANGE COUGH DROPS

menthol lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:44237-020
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.5 mg in 2.5

## Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SUGARCANE (UNII: 81H2R5AOH3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GREATER GALANGAL (UNII: 7Y64R856MB)	
HYSSOPUS OFFICINALIS WHOLE (UNII: 0IQW001KPE)	
CORDIA SEBESTENA FLOWER (UNII: LM8F18O4OJ)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
DEXTROSE (UNII: IY9XDZ35W2)	
LONG PEPPER (UNII: 2NMG4EA7B1)	
JUSTICIA ADHATODA LEAF (UNII: HH159XOV81)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	17mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44237-020-16	2 in 1 CARTON		
1		9 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part341	01/01/2015	
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**Labeler** - Herbion Pakistan (Pvt) Ltd (645482936)

**Registrant** - Herbion Pakistan (Pvt) Ltd (645482936)

**Establishment**

Name	Address	ID/FEI	Business Operations
Herbion Pakistan (Pvt) Ltd		645482936	manufacture(44237-020)

Revised: 1/2015

Herbion Pakistan (Pvt) Ltd