

## **HERBION NATURALS MINT 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



**Información del medicamento:**  
 Principio activo (en cada pastilla):  
 Mentol / Anestésico bucal

**Uso:**  
 Este medicamento se debe utilizar para aliviar la tos y el dolor de garganta. No se debe utilizar para tratar la infección o el resaca. Consulte a su médico si los síntomas persisten o empeoran.

**Advertencias:**  
 Evite el alcohol y los alimentos que contengan cafeína al tomar este medicamento. No se debe utilizar si se está tomando otros medicamentos que contengan mentol o anestésicos bucales.

**Condiciones de uso:**  
 Este medicamento se debe utilizar para aliviar la tos y el dolor de garganta. No se debe utilizar para tratar la infección o el resaca. Consulte a su médico si los síntomas persisten o empeoran.

**Otra información:**  
 Este medicamento se debe utilizar para aliviar la tos y el dolor de garganta. No se debe utilizar para tratar la infección o el resaca. Consulte a su médico si los síntomas persisten o empeoran.

**Exhibición:**  
 Este medicamento se debe utilizar para aliviar la tos y el dolor de garganta. No se debe utilizar para tratar la infección o el resaca. Consulte a su médico si los síntomas persisten o empeoran.

**Preguntas o comentarios?**  
 Llame al 1-800-445-1234 para más información.

Herbion **COUGH drops** ALL NATURAL

Relieves Cough & Soothes Sore Throat

Menthol  
 ✓ Cough Suppressant  
 ✓ Oral Anesthetic

No Added Color

Mint

18 Drops

Batch No.  
 Lote No.  
 Mfg. Date  
 Fecha de fabricación  
 Expiry Date  
 Fecha de caducidad

1-800-445-1234

Herbion **PARA LA TOS pastillas**

Alivian la Tos y el dolor de garganta

Herbion USA, Inc.  
 1100 W. 15th Street, Suite 100  
 Fort Lauderdale, FL 33304  
 Phone: 1-800-445-1234

Herbion **PARA LA TOS pastillas**

Alivian la Tos y el dolor de Garganta

COMPLETAMENTE NATURAL

FORMULA HERBION

Sin colorantes

Mentol  
 ✓ Antitusivo  
 ✓ Anestésico bucal

Menta  
 18 Pastillas

Herbion **COUGH drops**

Relieves Cough & Soothes Sore Throat

Herbion USA, Inc.  
 1100 W. 15th Street, Suite 100  
 Fort Lauderdale, FL 33304  
 Phone: 1-800-445-1234

**Drug Facts:**  
 Active ingredient (in each drop):  
 Menthol / Oral Anesthetic

**Warnings:**  
 For temporary relief of occasional minor throat pain, sore throat and cough associated with the common cold.

**Directions:**  
 Adults and children 2 years of age and over: Dissolve 1 drop slowly in mouth. Repeat every 4 hours as needed or as directed by a doctor.

**Other information:**  
 Patients should not use Herbion drops without the advice of a physician and should monitor glucose levels closely when taking drops as they may alter blood glucose levels.

**Drug Facts (Continued):**  
 Active ingredients: Menthol, Orange Oil, Clove Oil, Eucalyptus Oil, Lemon Oil, Peppermint Oil, Thyme Oil, Licorice Root, Liquid Glucose, Long Pepper Fruit, Natural Flavors, Thymol.

**Questions or comments?**  
 1-800-445-1234, Monday through Friday, 9am-5pm.

80 mm

80 mm

USA

80 mm



# HERBION NATURALS MINT COUGH DROPS

menthol lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:44237-021
<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>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44237-021-16	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
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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(44237-021)

Revised: 1/2015

Herbion Pakistan (Pvt) Ltd