

## **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**

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Cough Suppressant / Oral Anesthetic

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### **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 Flavors, 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**

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

Made in Pakistan

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### **Principal Display Panel**

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Herbion Naturals

Relieves **Cough** and Soothes **Sore Throat**

NATURAL CARE

cough drops

Menthol

|                    |             |
|--------------------|-------------|
| -Cough Suppressant | Honey Lemon |
| -Oral Anesthetic   | 18 Drops    |

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**Drug Facts** (Continued)

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**Herbion**  
NATURAL S

Relieves **Cough &**  
Soothes **Sore Throat**

◦ NATURAL CARE ◦

# COUGH drops



No Added Color

**Menthol**

- ✓ Cough Suppressant
- ✓ Oral Anesthetic

**Honey Lemon**  
**18 Drops**

**COUGH drops**  
Relieves Cough &  
Soothes Sore Throat

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Batch No. :

Mfg. Date :

Expiry Date :



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|-----------------------------------|-------------------------------------|
| Menthol, 5.5 mg                   | Cough Suppressant / Oral Anesthetic |

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**Herbion**  
NATURAL S

**COUGH drops**  
Relieves  
Soothes S

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# HERBION NATURALS HONEY LEMON

menthol lozenge

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:44237-016 |
| 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: IY9XDZ35W2)                   |          |
| ASCORBIC ACID (UNII: PQ6CK8PD0R)              |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)    |          |
| EUCALYPTUS OIL (UNII: 2R04ONI662)             |          |
| JUSTICIA ADHATODA LEAF (UNII: HH159XOV81)     |          |
| LONG PEPPER (UNII: 2NMG4EA7B1)                |          |
| CORDIA SEBESTENA FLOWER (UNII: LM8F18O4OJ)    |          |
| GREATER GALANGAL (UNII: 7Y64R856MB)           |          |
| HYSSOPUS OFFICINALIS WHOLE (UNII: 0IQW001KPE) |          |
| LICORICE (UNII: 61ZBX54883)                   |          |

| Product Characteristics |              |              |          |
|-------------------------|--------------|--------------|----------|
| Color                   | white        | 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:44237-016-18 | 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                                  | 04/15/2014           |                    |

**Labeler** - Herbion Pakistan (Pvt.) Ltd (645482936)

## Establishment

| Name                        | Address | ID/FEI    | Business Operations    |
|-----------------------------|---------|-----------|------------------------|
| Herbion Pakistan (Pvt.) Ltd |         | 645482936 | manufacture(44237-016) |

Revised: 8/2014

Herbion Pakistan (Pvt.) Ltd