

HERBION NATURALS HONEY LEMON 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.

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:

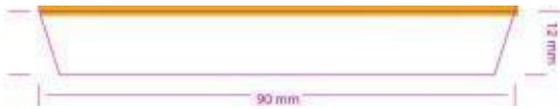
- diabetic patients should not use Herbion drops without the advice of a physician and they should monitor glucose levels closely while taking drops as they may alter blood-glucose levels
- store in a cool, dry place, below 77°F
- protect from heat and light

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 HONEY LEMON COUGH DROPS

menthol lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:44237-019 |
| Route of Administration | 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

| | | | |
|-----------------|--------------|---------------------|----------|
| 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:44237-019-18 | 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 |
|--------------------|--|----------------------|--------------------|
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|---------------------|---------|------------|--|
| OTC monograph final | part341 | 12/24/2014 | |
|---------------------|---------|------------|--|

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(44237-019) |

Revised: 12/2014

Herbion Pakistan (Pvt) Ltd