

HERBION NATURALS ORANGE - 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.

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 Orange Color, Artificial Orange Flavor, Artificial Mint 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 - 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

Herbion Naturals

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

NATURAL CARE

cough drops

Menthol

-Cough suppressant	Orange
-Oral anesthetic	18 Drops

25 mm

90 mm

12 mm

12 mm

Drug Facts (Continued)

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Herbion
NATURALS

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NATURAL CARE
COUGH
drops



Menthol
✓ Cough Suppressant
✓ Oral Anesthetic

Orange
18 Drops

COUGH
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Relieves Cough &
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80 mm

Batch No. :
Mfg. Date :
Expiry Date :



USA

Herbion

COUGH
drops
Relieves Cough &
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25 mm

90 mm

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44237-100
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)	
GREATER GALANGAL (UNII: 7Y64R856MB)	
HYSSOPUS OFFICINALIS WHOLE (UNII: 0IQW001KPE)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CORDIA SEBESTENA FLOWER (UNII: LM8F18O4OJ)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	17mm
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44237-100-18	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	12/01/2013	

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

Establishment

Name	Address	ID/FEI	Business Operations
Herbion Pakistan (Pvt.) Ltd		645482936	manufacture(44237-100)

Revised: 11/2013

Herbion Pakistan (Pvt.) Ltd