

HERBION NATURALS ORANGE COUGH DROPS SUGAR FREE- 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:

- store in a cool, dry place, below 77°F
- protect from heat and light

Inactive Ingredients:

Ascorbic Acid, Natural orange flavor, Stevia, Citric acid, Eucalyptus oil, Greater galangal Rhizome, Hyssop, Large-leaf geiger tree Fruit, Licorice Root, Isomalt, Long pepper Fruit, Malabar nut tree Leaf

Questions or Comments?

1-888-(OK-HERBION) 654-3724, Monday through Friday 9am - 5pm EST



HERBION NATURALS ORANGE COUGH DROPS SUGAR FREE

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44237-032
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)	
STEVIA LEAF (UNII: 6TC6NN0876)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GREATER GALANGAL (UNII: 7Y64R856MB)	
CORDIA SEBESTENA FLOWER (UNII: LM8F18O4OJ)	
HYSSOPUS OFFICINALIS WHOLE (UNII: 0IQW001KPE)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ISOMALT (UNII: S870P55O2W)	
LONG PEPPER (UNII: 2NMG4EA7B1)	
JUSTICIA ADHATODA LEAF (UNII: HH159XOV81)	

Product Characteristics

Color	white	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:44237-032-25	25 in 1 POUCH	02/10/2017	
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/10/2017	

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(44237-032)