

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

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 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

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

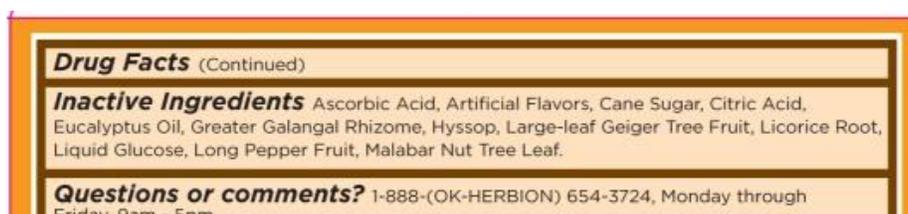
Relieves **Cough** and Soothes **Sore Throat**

NATURAL CARE

cough drops

Menthol

-Cough suppressant Orange
 -Oral anesthetic 18 Drops



Herbion
NATURAL S

Relieves Cough &
Soothes Sore Throat

• NATURAL CARE •

COUGH drops



No
Added
Color



Menthol

- ✓ Cough Suppressant
- ✓ Oral Anesthetic

Orange
18 Drops

COUGH
drops

Relieves Cough &
Soothes Sore Throat

Herbion
NATURAL S

Manufactured for:
Herbion USA Inc.
Williamsville, NY 14221
1-888-COOL-HERBION-654-3724
info.us@herbion.com
www.herbion.com
Made in Pakistan

Batch No. :

Mfg. Date :

Expiry Date :



4607006674677

Drug Facts:

Active Ingredient (in each drop):

Menthol, 5.5 mgCough Suppressant / Oral Anesthetic

Purpose

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

Herbion
NATURAL S

COUGH
drops

Relieves Cough &
Soothes Sore Throat

1 G MM

1 G MM

PW3 9.1

HERBION NATURALS ORANGE

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44237-015
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)	
CORDIA SEBESTENA FLOWER (UNII: LM8F18O4OJ)	
LICORICE (UNII: 61ZBX54883)	

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:44237-015-18	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(44237-015)

Revised: 8/2014

Herbion Pakistan (Pvt.) Ltd