HERBION NATURALS MINT 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, 6 mg

Purpose

Cough Suppresant, Oral Anesthetic

Uses

• Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold.

Warnings

- A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
- Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.
- If breast-feeding or pregnant, consult your physician before using.
- Keep this and all drugs out of the reach of children.

Directions

Adults and children 12 years and over: Take 1-2 drops every 2 to 3 hours. **Children 6 years to under 12 years:** Take 1 drop every 5 to 6 hours not more than 4 drops in 24 hours

Children under 6 years of age: Consult your doctor.

Other Information

- Store in a cool, dry place, below 77 degrees F.
- Protect from heat and light.
- Diabetic patients should not use Herbion drops without the advice of physician and they should monitor glucose level closely while taking drops as it may alter blood-glucose levels.

Inactive Ingredients

Ascorbic Acid, Citric Acid, Eucalyptus Oil, Menthol Flavor, Hyssop, Large-leaf Geiger Tree Fruit, Lesser Galangal Rhizome, Licorice Root, Long Pepper Fruit, Malabar Nut Leaf, Cane Sugar, Sweet Violet Leaf and Flower, Water

Side Panel:

Manufactured for:

Herbion USA Inc.

Williamsville, NY 14221 1-888-(OK-HERBION)-654-3724 Info.us@herbion.com www.herbion.com

Principal Display Panel:

Herbion Naturals

Relieves Cough and Soothes Sore Throat

All Natural

Cough Drops

Herbal Formula

Mint

18 Drops



menthol lozenge

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:44237-009

Route of Administration ORAL

Active Ingredient/Active Moiety

П	J	3		
		Ingredient Name	Basis of Stren	ngth Strength
	MENTHOL (UNII: L7T10EII	3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 mg

Inactive Ingredients		
Ingredient Name	Strength	
ASCORBIC ACID (UNII: PQ6CK8PD0R)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
EUCALYPTUS OIL (UNII: 2R040NI662)		
HYSSOPUS OFFICINALIS FLOWERING TOP (UNII: X7HKN4FOJI)		
LESSER GALANGAL ROOT (UNII: 42LD90786Y)		
LICORICE (UNII: 61ZBX54883)		
LONG PEPPER (UNII: 2NMG4EA7B1)		
JUSTICIA ADHATODA LEAF (UNII: HH159 XOV81)		
SUCROSE (UNII: C151H8M554)		
VIOLA ODORATA LEAF (UNII: 3X41NMU9FW)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics Color white Score no score Shape ROUND Size 17mm Flavor MINT Imprint Code ; Contains

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:44237-009-18	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	0 1/0 1/20 13	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Herbion Pakistan (Pvt.) Ltd.		645482936	relabel(44237-009), manufacture(44237-009)	

Revised: 12/2012 Herbion Pakistan (Pvt.) Ltd.