PALATOS EXPECTORANTE- guaifenesin liquid
All Pharma, LLC

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.

Acvtive ingredients: (in each 5ml) **Purpose**

Guaifenesin 100 mg ..... Expectorant

Purpose

Expectorant

Uses

- Help loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.

Warnings

Do not exceed recommended dosage

Do not use

- if you have a chronic pulmonary disease or shortness of breath unless directed by a doctor

Ask the doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask the doctor if

- Nervoisness, dizziness or sleeplessness occurs.
- Cough persists for more than 1 week, tends to recur, or accompanied by fever, rash or persistent headache. A persistent cough may be sign of a serious condition

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not take more than 6 doses in any 24-hour period
- Shake well before use

Age	**Dose**
Adults and children 12 years and over	10 mL (2 tsps) every 4 hours
Children 6 to under 12 years of age.	5 mL (1 tsps) every 4 hours
Children under 6 years of age	**Do not use**

Inactive ingredients

Blue cohosh, citric acid, echinacea, eucalyptus oil, ginkgo biloba, glycerin, gold seal root, honey flavor, horehound herb, licorice root, menthol, mullein, myrrh, potassium sorbate, slippery elm bark, sodium benzoate, propylene glycol, water, sodium chloride, sucralose, wild cherry bark and zinc sulfate.

Palatos

PALATOS EXPECTORANTE

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53149-2000
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CAULOPHYLLUM THALICTROIDES ROOT (UNII: JTJ6HH6YEH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	

EUCALYPTUS CAMALDULENSIS LEAF OIL (UNII: SN6D1J15I6)	
GINKGO BILOBA WHOLE (UNII: 660486U6OI)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
HOREHOUND (UNII: K08036XEJV)	
LICORICE (UNII: 61ZBX54883)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
VERBASCUM DENSIFLORUM LEAF (UNII: 9936O846LI)	
MYRRH (UNII: JC71GJ1F3L)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PRUNUS SEROTINA BARK (UNII: 5D48E975HA)	
ZINC SULFATE, UNSPECIFIED FORM (UNII: 89DS0H96TB)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53149-2000-6	1 in 1 BOX	01/01/2019	
1		177 mL in 1 BOTTLE; 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	01/01/2019	

Labeler - All Pharma, LLC (117605075)

Establishment

Name	Address	ID/FEI	Business Operations
All Pharma, LLC		117605075	MANUFACTURE(53149-2000)