GUAIFENESIN- guaifenesin solution
Akorn

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

Each 5 mL (1 teaspoonful) contains:

Guaifenesin ..... 100 mg

Inactive ingredients

Acesulfame K, artificial cherry & vanilla flavor, aspartame, hypromellose, menthol, methylparaben, potassium sorbate, purified water. Citric acid may be used to adjust pH.

Purpose

Expectorant

Uses

Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings

Ask a 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 a doctor if

- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- you are hypersensitive to any of the ingredients

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.

Professional Note: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Directions

Follow dosage below or use as directed by a physician.

- do not take more than 6 doses in any 24-hour period

age	dose
adults and children 12 years and over	10 to 20 mL (2 to 4 teaspoonfuls) every 4 hours
children 6 years to under 12 years	5 to 10 mL (1 to 2 teaspoonfuls) every 4 hours
children 2 to under 6 years of age	2.5 to 5 mL (1/2 to 1 teaspoonful) every 4 hours
children under 2 years of age	ask a doctor

How Supplied:

Guaifenesin Oral Solution is a clear viscous liquid with a slight cherry odor supplied in the following oral dosage forms: 5 mL unit dose, 10 mL unit dose, 15 mL unit dose in trays of 10 and 4 fl. oz. (118 mL) bottle

Phenylketonurics: contains phenylalanine 8.4 mg per teaspoonful (5 mL)

STORAGE

Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F). [See USP] Protect from light.

Questions or comments?

Call **1-800-262-9010**.

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev.063:01 4/13

MG #29850

Package/Label Principal Display Panel

Delivers 15 mL

NDC 50383-063-15

GUAIFENESIN ORAL SOLUTION

300 mg/15 mL

Sugar Free/Alcohol Free

EXPECTORANT

SEE INSERT

FOR INSTITUTIONAL USE ONLY

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

GUAIFENESIN

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50383-063
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY (artificial cherry flavor) , VANILLA (artificial vanilla flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-063-06	4 in 1 CASE	03/07/2012	06/05/2017
1	NDC:50383-063-05	10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:50383-063-07	10 in 1 CASE	03/07/2012	
2		10 in 1 TRAY		
2		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:50383-	4 in 1 CASE	03/07/2012	06/05/2017

3	063-11	4 in 1 CASE	03/07/2012	06/05/2017
3	NDC:50383-063-10	10 in 1 TRAY		
3		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
4	NDC:50383-063-12	10 in 1 CASE	03/07/2012	
4		10 in 1 TRAY		
4		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
5	NDC:50383-063-17	4 in 1 CASE	03/07/2012	06/05/2017
5	NDC:50383-063-15	10 in 1 TRAY		
5		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
6	NDC:50383-063-18	10 in 1 CASE	03/07/2012	
6		10 in 1 TRAY		
6		15 mL in 1 CUP, UNIT-DOSE; 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	03/07/2012	

Labeler - Akorn (117696873)

Registrant - Akorn Operating Compnay LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	MANUFACTURE(50383-063) , PACK(50383-063)

Revised: 11/2022 Akorn