

VIRTUSSIN AC- codeine phosphate and guaifenesin liquid

A-S Medication Solutions

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.

Virtussin AC

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	Purpose
Codeine phosphate, USP 10 mg	Cough suppressant
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask your doctor before use if

- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product

- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.
- may cause or aggravate constipation

Stop use and ask a doctor if

- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

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

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

Directions

- do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information

Store at controlled room temperature 15°-30°C (59°-86°F).

You may report side effects by calling 1-888-848-3593 or FDA at 1-800-FDA-1088.

Inactive ingredients

Cherry flavor, citric acid, methylparaben, potassium citrate, potassium sorbate, propylparaben, propylene glycol, purified water, sorbitol, sucralose.

Manufactured for: Virtus Pharmaceuticals, LLC

Langhorne, PA 19047

1-888-848-3593

Made in USA

Rev. 07/2019

7270-0016

HOW SUPPLIED

Product: 50090-5398

NDC: 50090-5398-0 118 mL in a BOTTLE

VIRTUSSIN AC (CODEINE PHOSPHATE AND GUAIFENESIN) LIQUID



VIRTUSSIN AC

codeine phosphate and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-5398(NDC:69543-252)
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
citric acid monohydrate (UNII: 2968PHW8QP)	
methylparaben (UNII: A2I8C7HI9T)	
potassium citrate (UNII: EE90ONI6FF)	
potassium sorbate (UNII: 1VPU26JZZ4)	
propylparaben (UNII: Z8IX2SC1OH)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	

Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-5398-0	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	07/07/2015		

Labeler - A-S Medication Solutions (830016429)

Establishment			
Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5398)

Revised: 3/2021

A-S Medication Solutions