

## **VIRTUSSIN A/C- codeine phosphate and guaifenesin liquid**

**Virtus Pharmaceuticals**

*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.*

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### **Virtussin A/C**

#### ***Drug Facts***

<b><i>Active ingredients (in each 5 mL = 1 tsp)</i></b>	<b><i>Purpose</i></b>
Codeine phosphate, USP 10 mg	Antitussive
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	1 tsp (5 mL) every 4 hours, or as

age:	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.

### **PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

**NDC:** 69543-252-16

**Virtussin  
A/C**

**Antitussive  
Expectorant**

**CV**

**ALCOHOL-FREE / SUGAR-FREE**

**Each 5 mL (1 teaspoonful) contains:**

Codeine phosphate, USP 10 mg

Guaifenesin, USP 100 mg

**(WARNING: May be habit-forming)**

Tamper evident by foil  
seal under cap.

Do not use if foil seal is  
broken or missing.

**16 fl. oz. (473 mL)**

**VIRTUS®  
PHARMACEUTICALS**

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## Drug Facts (continued)

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Manufactured for: Virtus Pharmaceuticals, LLC  
Newtown, PA 18940  
1-888-848-3593  
Made in USA

Rev. 04/2017  
7270-0016



## VIRTUSSIN A/C

codeine phosphate and guaifenesin liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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:69543-252-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2015	
2	NDC:69543-252-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/07/2015	

**Labeler** - Virtus Pharmaceuticals (079659493)

Revised: 11/2017

Virtus Pharmaceuticals