

VIRTUSSIN A/C- codeine phosphate and guaifenesin liquid

Unit Dose Services

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.

Virtus in A/C

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	Purpose
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.

HOW SUPPLIED

Product: 50436-2520

NDC: 50436-2520-1 118 mL in a BOTTLE

VIRTUSSIN A/C (CODEINE PHOSPHATE AND GUAIFENESIN) LIQUID

NDC: 50436-2520-1 VIRTUSSIN A/C (Guaifenesin / Codeine Phosphate) 100/10 mg / 5 mL 4 fl.oz. (118 mL) Antitussive Expectorant		 ALCOHOL-FREE / SUGAR-FREE	NDC: 50436-2520-1 VIRTUSSIN A/C DRUG: (Guaifenesin / Codeine Phosphate) 100/10 mg / 5 mL 4 fl.oz. (118 mL) LOT: XXXXX EXP: XX/XX/XX
Each 5 mL (1 teaspoonful) contains: Codeine phosphate, USP 10 mg Guaifenesin, USP 100 mg (WARNING: May be habit-forming)			NDC: 50436-2520-1 VIRTUSSIN A/C DRUG: (Guaifenesin / Codeine Phosphate) 100/10 mg / 5 mL 4 fl.oz. (118 mL) LOT: XXXXX EXP: XX/XX/XX
Drug Facts Active ingredients (in each 5 mL = 1 tsp) Codeine phosphate, USP 10 mg Guaifenesin, USP 100 mg	Purpose Antitussive Expectorant	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.	
Uses • Temporarily relieves: • Cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants • Your cough to you sleep • Helps loosen phlegm (mucus) and thin bronchial secretions and the bronchial passageways of bothersome mucus and make cough 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		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.	
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.		MFG NDC: 69543-252-04 MFG LOT: XXXXXX SERIAL: XXXXX000003 LOT: XXXXX EXP: XX/XX/XX	

VIRTUSSIN A/C			
codeine phosphate and guaifenesin liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-2520(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:50436-2520-1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/08/2019	

Marketing Information

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

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-2520) , RELABEL(50436-2520)

Revised: 1/2019

Unit Dose Services