

VIRTUSSIN DAC- codeine phosphate, guaifenesin, and pseudoephedrine hydrochloride 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.

Virtussin DAC

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	Purpose
Codeine phosphate, USP 10 mg	Cough Suppressant
Guaifenesin, USP 100 mg	Expectorant
Pseudoephedrine HCl, USP 30 mg	Nasal Decongestant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves nasal congestion due to the common cold
- temporarily restores freer breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- calms the cough control center and relieves coughing

Warnings

Ask your doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with excessive phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Do not use

- in a child under 2 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease),

or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

- if you or your child has a chronic pulmonary disease or shortness of breath
- if your child is taking other drugs, unless directed by a doctor

When using this product

- **do not use more than directed**
- may cause drowsiness
- constipation may occur or be aggravated

Stop use and ask a doctor if

- you get nervous, dizzy, or have trouble sleeping
- 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.

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 4 doses in any 24 hour period.

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.

Attention: A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

Other information

Each tsp (5 mL) contains 3 mg sodium.

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

Alcohol, caramel flavor, cherry flavor, citric acid, FD&C red #40, glycerin, menthol flavor, potassium citrate, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol 70% solution.

Manufactured for:
Virtus Pharmaceuticals, LLC
Langhorne, PA 19047
1-888-848-3593

Rev. 11/2018
Made in USA
7269-0004

Principal Display Panel - 118 mL Bottle Label

IMPRINT AREA

NDC: 69543-253-04

Virtussin DAC

**Cough Suppressant
Expectorant
Nasal Decongestant**

SUGAR FREE • 2.1% (v/v) ALCOHOL

Each 5 mL (1 teaspoonful) contains:
Codeine phosphate, USP 10 mg
Guaifenesin, USP 100 mg
Pseudoephedrine HCl, USP 30 mg
(WARNING: May be habit-forming)

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

4 fl. oz. (118 mL)

VIRTUS
PHARMACEUTICALS

3 69543 25304 16

Drug Facts (Continued)
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VARNISH AREA

NDC: 69543-253-04

Virtussin DAC

**Cough Suppressant
Expectorant
Nasal Decongestant**

CV

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Do not use if foil seal is broken or missing.

4 fl. oz. (118 mL)

VIRTUS®
PHARMACEUTICALS

VIRTUSSIN DAC

codeine phosphate, guaifenesin, and pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69543-253
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
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KOOR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CARAMEL, CHERRY, MENTHOL	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69543-253-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2019	

Labeler - Virtus Pharmaceuticals (079659493)

Revised: 7/2021

Virtus Pharmaceuticals