

**DAYTIME SEVERE- acetaminophen, dextromethorphan hydrobromide,
guaifenesin, phenylephrine hydrochloride solution
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

CVS Pharmacy, Inc. Daytime Severe Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- headache
- sore throat
- fever
- cough due to minor throat and bronchial irritation
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen

- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- **each 15 mL contains:** sodium 15 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C red #40, FD&C yellow #6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions?

1-800-719-9260

Package/Label Principal Display Panel

CVS Health®

Compare to the active ingredients in Vicks® DayQuil® Severe Honey Flavor

Daytime Severe

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

GUAIFENESIN

Expectorant

PHENYLEPHRINE HCl

Nasal decongestant

Relieves:

Headache, Fever, Sore throat, Minor aches & pains, Chest congestion, Nasal & Sinus congestion, Sinus pressure, Cough

Thins & loosens mucus

COLD & FLU

Honey Flavor

ANTIHISTAMINE FREE

12 FL OZ (355 mL)



Compare to the active ingredients in Vicks® DayQuil® Severe Honey Flavor*

NDC 51316-613-40

Daytime Severe

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COLD & FLU



Honey Flavor

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12 FL OZ (355 mL)

: 51U40 17 F1

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DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

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#350947

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Uses temporarily relieves common cold/flu symptoms: ■ sinus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ headache ■ sore throat ■ fever ■ cough due to minor throat and bronchial irritation ■ reduces swelling of nasal passages ■ promotes nasal and/or sinus drainage ■ temporarily restores freer breathing through the nose ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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Liver warning: This product contains acetaminophen. Severe liver damage may occur if ■ adult takes more than 4,000 mg of acetaminophen in 24 hours ■ child takes more than 5 doses in 24 hours ■ taken with other drugs containing acetaminophen ■ adult has 3 or more alcoholic drinks every day while using this product
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away.

PEEL BACK AT CORNER FOR MORE INFORMATION

: 51U40 17 B1

Drug Facts (continued)

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ADHESIVE AREA • NO VARNISH • NO TYPE

Drug Facts (continued)

Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

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AL
NO COATING

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- high blood pressure ■ diabetes
- thyroid disease ■ cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
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Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

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Other information ■ each 15 mL contains: sodium 15 mg ■ store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C red #40, FD&C yellow #6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions? 1-800-719-9260

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Severe Honey Flavor.

NO COAT

DAYTIME SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-613
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor	HONEY, MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-613-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/28/2023	

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)