DG HEALTH COLD AND FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution Dolgencorp Inc

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.

Dolgencorp, LLC Cold & Flu 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:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- 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
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- 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?

1-888-309-9030

Package/Label Principal Display Panel

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

DG™ health

Maximum Strength

Cold & Flu

Severe

Acetaminophen

Phenylephrine HCI

Dextromethorphan HBr

Guaifenesin

Pain Reliever, Fever Reducer, Nasal Decongestant

Cough Suppressant, Expectorant

- Headache, Fever, Sore throat, Minor Aches & Pains
- Chest Congestion, Thins & Loosens Mucus
- Nasal/Sinus Congestion, Sinus Pressure
- Cough

Daytime Relief

Honey Flavor

Non-drowsy

12 FL OZ (355 mL)

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

DG™health

Maximum Strength

Cold & Flu Severe

Acetaminophen
Phenylephrine HCl
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Pain Reliever, Fever Reducer, Nasal Decongestant Cough Suppressant, Expectorant

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Daytime Relief

Honey Flavor

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12 FL 0Z (355 mL)

: 51U4D VT F1

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

DISTRIBUTED BY OLD EAST MAIN CO. 100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

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www.StopMedicineAbuse.org

- 100% --Satisfaction Guaranteed! (888) 309-9030

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Drug Facts

Acetaminophen

Active ingredients (in each 15 mL)

Pain reliever/fever reducer

Purpose

325 mg..... Dextromethorphan HBr

10 mg......Cough suppressant Guaifenesin 200 mg.....Expectorant Phenylephrine HCl 5 mg...Nasal decongestant

Uses temporarily relieves common cold/flu symptoms: ■ sinus congestion and pressure

inasal congestion in minor aches and pains in headache in 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

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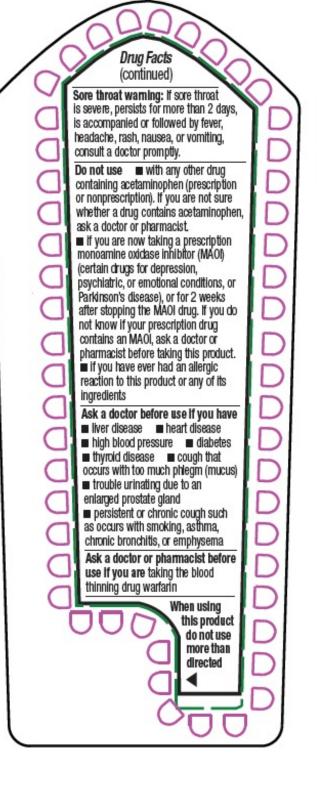
Severe liver damage may occur if adult takes more than 4,000 mg of acetaminophen in 24 hours child takes more than 5 doses in 24 hours taken with other drugs containing acetaminophen adult has 3 or more alcoholic drinks every day while using this product

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 VT B1



Drug Facts (continued)

Stop use and ask a doctor if wou 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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Directions ■ take only as directed – see

Overdose warning ■ only use the dose cup

provided ■ do not exceed 4 doses per 24 hrs

adults & children	30 mL every 4 hrs
12 yrs & over	20
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
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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?1-888-309-9030

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

DG HEALTH COLD AND FLU SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-576
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:55910-576- 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 final	part341	06/28/2023	

Labeler - Dolgencorp Inc (068331990)

Revised: 8/2023 Dolgencorp Inc