DG HEALTH COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution Dolgencorp, LLC

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 Relief 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 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments?

1-888-309-9030

Package/Label Principal Display Panel

Compare to active ingredients of Vicks® DayQuil® Severe Cold & Flu

Maximum Strength Relief Day Time Severe Cold & Flu Relief Acetaminophen Phenylephrine HCl Dextromethorphan HBr Guaifenesin Pain Reliever, Fever Reducer **Cough Suppressant** Expectorant Nasal Decongestant **Original Flavor** Non drowsy Alcohol free Antihistamine free 8 FL OZ (237 mL)



	Drug Facts (continued)	Drug Facts (continued)				
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	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.	adults & children 12 yrs & over 30 mL every 4 hrs				
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DG HEALTH COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559	10-737	
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingred	dient Name		Basis of Stre	ength	Strength	
					22E ma	

ACETAMINOPHEN	(UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362C	9ITL9D) ACETAMINOPHE	N 325 mg in 15 mL	
DEXTROMETHORP (DEXTROMETHORPH/		I DE (UNII: 9D2RTI9KYH) S)	DEXTROMETHO HYDROBROMIDI	- 5	
GUAIFENESIN (UNII	: 495W7451VQ) (GU	AIFENESIN - UNII:495W7451V0	Q) GUAIFENES IN	200 mg in 15 mL	
PHENYLEPHRINE H UNII:1WS297W6MV)	IYDROCHLORIDE (U	JNII: 04JA59TNSJ) (PHENYLEP	HRINE - PHENYLEPHRINE HYDROCHLORIE	- 5	
Inactive Ingre	dients				
		Ingredient Name		Strength	
BUTYLATED HYDR	OXYANISOLE (UNII:	REK4960K2U)			
EDETATE DISODIU	M (UNII: 7FLD91C86	K)			
FD&C YELLOW NO	. 6 (UNII: H77VEI934	48)			
GLYCERIN (UNII: PD	C6A3C0OX)				
MENTHOL, UNSPE	CIFIED FORM (UNII:	L7T10EIP3A)			
SODIUM PHOSPHA	TE, MONOBASIC,	UNSPECIFIED FORM (UNII:	3980JIH2SW)		
POLYETHYLENE G	LYCOL, UNSPECIFI	ED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYC	OL (UNII: 6DC9Q167	V3)			
WATER (UNII: 059Q	F0KO0R)				
SACCHARIN SODIU	IM (UNII: SB8ZUX40	TY)			
SUCROSE (UNII: C1	51H8M554)				
XANTHAN GUM (UN	III: TTV12P4NEE)				
Product Chara	acteristics				
Color	ORANGE (c	lear)	Score		
Shape			Size		
Flavor	FRUIT, MEN	THOL	Imprint Code		
Contains					
Packaging					
# Item Code	Packa	ge Description	Marketing Start Date	Marketing End Date	
1 NDC:55910-737- 34	237 mL in 1 BOTTLE Product	; Type 0: Not a Combination	05/20/2014		
Marketing	Information				
Marketing		Number or Monograph	Marketing Star	t Marketing End	
	ADDIICATION				
Category	Application	Citation	Date	Date	
Category OTC monograph fina			-	-	

Labeler - Dolgencorp, LLC (068331990)