

DG HEALTH NIGHT TIME SEVERE COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride 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 Night Time Severe Cold & Flu Relief Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine succinate 12.5 mg

Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- headache
- runny nose and sneezing
- sore throat
- cough to help you sleep
- 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

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- 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 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- **each 30 mL contains:** sodium 42 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C blue #1, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose

Questions?

1-888-309-9030

Package/Label Principal Display Panel

Compare to the active ingredients of Vicks[®] NyQuil[®] Severe + VapoCOOL[™]

DG[™] |health

Maximum Strength

Night Time Severe Cold & Flu Relief

Acetaminophen

Phenylephrine HCl

Doxylamine Succinate

Dextromethorphan HBr

Pain Reliever, Fever Reducer

Nasal Decongestant

Antihistamine

Cough Suppressant

Vapor Ice[®]

ALCOHOL 10%

12 FL OZ (355 mL)

Compare to the active ingredients of Vicks® NyQuil® Severe+VapoCOOL™*

DG™ | health

Maximum Strength
Night Time Severe
Cold & Flu Relief

Acetaminophen
Phenylephrine HCl
Doxylamine Succinate
Dextromethorphan HBr

Pain Reliever, Fever Reducer
Nasal Decongestant
Antihistamine
Cough Suppressant

Vapor Ice®

ALCOHOL 10%

12 FL OZ (355 mL)

: 59B40 VT F2

**DO NOT USE
IF PRINTED NECKBAND
IS BROKEN OR MISSING**

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A1298

Drug Facts

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

**PEEL BACK AT
CORNER FOR MORE
INFORMATION**

: 59B40 VT B1

Drug Facts
(continued)

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Ask a doctor before use if you have ■ liver disease ■ heart disease

ADHESIVE AREA
• NO VARNISH • NO TYPE

Drug Facts
(continued)

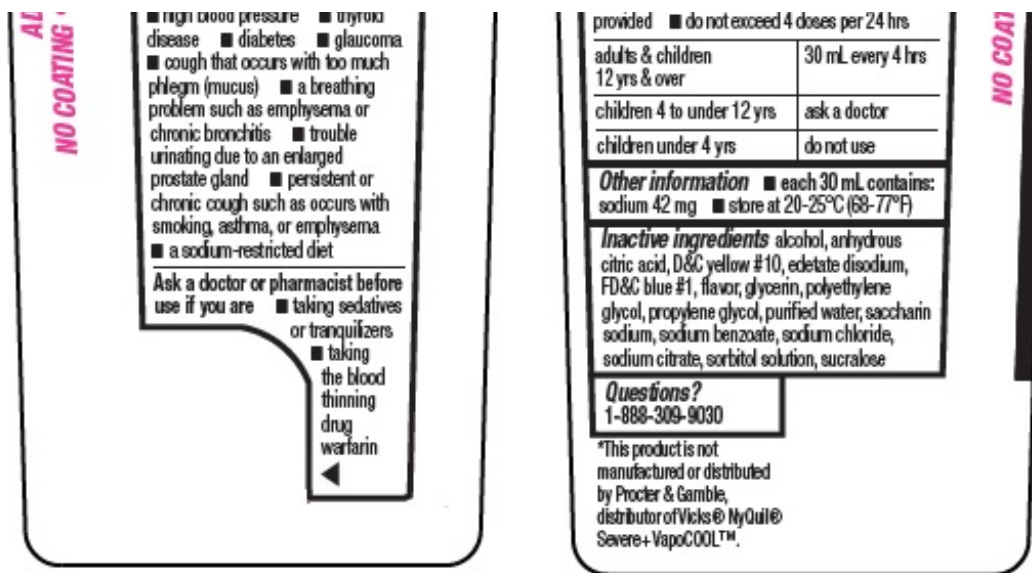
When using this product ■ do not use more than directed ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness

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Directions ■ take only as directed - see Overdose warning ■ only use the dose cup

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acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-572
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-572-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2020	
2	NDC:55910-572-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/10/2020	

Labeler - Dolgencorp, LLC (068331990)

Revised: 1/2023

Dolgencorp, LLC