DG HEALTH NIGHT TIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled 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 Cold & Flu Relief Drug Facts

Active ingredients (in each liquid cap)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

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, lasts 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

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

When using this product

- 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

- pain 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
- do not exceed 4 doses per 24 hours

adults & children 12 yrs & over	2 liquid caps with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Inactive ingredients

edible dye-free ink*, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments?

1-888-309-9030

Package/Label Principal Display Panel

Compare to the active ingredients of Vicks® NyQuil® Cold & Flu

Night Time Cold & Flu Relief

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

Dye-Free

Multi-Symptom Relief of:

Aches, Fever, Sore Throat

Sneezing, Runny Nose

Cough

8 Liquid Caps

Actual Liquid Cap Size



MADE IN CANADA

DISTRIBUTED BY DOLGENCORP, LLC 100 MISSION RIDGE GOODLETTSVILLE, TN 37072 USA

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





Compare to the active ingredients of Vicks® NyQuil® Cold & Flu**



Night Time Cold & Flu Relief

Acetaminophen, Dextromethorphan HBr, **Doxylamine Succinate**

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

Multi-Symptom Relief of:

- Aches, Fever, Sore ThroatSneezing, Runny Nose
- Cough



8 Liquid Caps

Actual Liquid Cap Size

Procter & Gamble, distributor of m anufactured or distributed by

**This product is not

/icks® NyQuil® Cold & Flu

Inactive ingredients edible dye-free ink*,

Orug Facts (continued)

Drug Facts DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Active ingredients (in each liquid cap) Purpose Acetaminophen 325 mg......Pain reliever/fever reducer Dextromethorphan HBr 15 mg......Cough suppressant Doxylamine succinate 6.25 mg......Antihistamine *Uses* temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ minor aches and pains ■ runny nose and sneezing ■ sore throat ■ headache ■ fever 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, lasts 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. 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 ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem such as emphysema or chronic bronchitis ■ liver disease ■ glaucoma persistent or chronic cough as occurs with smoking, asthma, or emphysema ■ trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin When using this product ■ excitability may occur, especially in children ■ be careful when driving a motor vehicle or operating machinery ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness marked drowsiness may occur 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 ■ do not exceed 4 doses per 24 hours adults & children 12 yrs & over 2 liquid caps with water every 6 hrs

ask a doctor

do not use

children 4 to under 12 yrs

children under 4 yrs

DG HEALTH NIGHT TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-421
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	

Inactive Ingredients			
Ingredient Name	Strength		
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			
PO VIDO NE (UNII: FZ989 GH9 4E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	YELLOW (clear)	Score	no score	
Shape	OVAL	Size	21mm	
Flavor		Imprint Code	6L0	
Contains				

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-421-51	4 in 1 CARTON	06/19/2018	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/19/2018	

Labeler - Dolgencorp, LLC (068331990)

Revised: 12/2019 Dolgencorp, LLC