

**DG HEALTH COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl  
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.*

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**Dolgencorp, LLC Cold & Flu Relief Drug Facts**

**Active ingredients (in each softgel) – Nighttime Cold & Flu**

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Active ingredients (in each softgel) – Daytime Cold & Flu**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purpose – Nighttime Cold & Flu**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Purpose – Daytime Cold & Flu**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Uses – Nighttime Cold & Flu**

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

**Uses – Daytime Cold & Flu**

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- 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.
- 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 – Nighttime Cold & Flu**

- 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 before use if you have – Daytime Cold & Flu**

- liver disease
- heart disease

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

**Ask a doctor or pharmacist before use if you are – Nighttime Cold & Flu**

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

**Ask a doctor or pharmacist before use if you are – Daytime Cold & Flu**

taking the blood thinning drug warfarin

**When using this product – Nighttime Cold & Flu**

- 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

**When using the product – Daytime Cold & Flu**

do not use more than directed

**Stop use and ask a doctor if – Nighttime Cold & Flu**

- 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.

**Stop use and ask a doctor if – Daytime Cold & Flu**

- 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 – Nighttime Cold & Flu**

- take only as directed – see overdose warning
- do not exceed 4 doses per 24 hrs

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

**Directions – Daytime Cold & Flu**

- take only as directed – see overdose warning
- do not exceed 4 doses per 24 hrs

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

**Other information**

- store at 20-25°C (68-77°F)

**Inactive ingredients – Nighttime Cold & Flu**

D&C yellow no. 10, edible ink\*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

**Inactive ingredients – Daytime Cold & Flu**

edible ink\*, FD&C red no. 40, FD&C yellow no. 6, 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® DayQuil® and Vicks® NyQuil® Cold & Flu Day Time

Cold & Flu Relief

Acetaminophen,

Dextromethorphan HBr,

Phenylephrine HCl

Pain Reliever, Fever Reducer,

Cough Suppressant, Nasal Decongestant

Multi-Symptom Relief of:

Aches, Fever, Sore Throat – Nasal Congestion

Cough – Non-Drowsy

32 Softgels

Actual Softgel Size

Night Time

Acetaminophen,

Dextromethorphan HBr,

Doxylamine Succinate

Pain Reliever, Fever Reducer,

Cough Suppressant, Antihistamine

Multi-Symptom Relief of:

Aches, Fever, Sore Throat

Sneezing, Runny Nose – Cough

16 Softgels

Actual Softgel Size



Nighttime Cold & Flu		Daytime Cold & Flu	
<b>Drug Facts</b>		<b>Drug Facts</b>	
<b>Active ingredients (in each softgel)</b>	<b>Purpose</b>	<b>Active ingredients (in each softgel)</b>	<b>Purpose</b>
Acetaminophen 325 mg.....	Pain reliever/fever reducer	Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant	Dextromethorphan HBr 10 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine	Phenylephrine HCl 5 mg.....	Nasal decongestant
<b>Uses</b> temporarily relieves common cold/flu symptoms: <ul style="list-style-type: none"> <li>■ cough due to minor throat and bronchial irritation</li> <li>■ minor aches and pains ■ sore throat ■ headache</li> <li>■ runny nose and sneezing ■ fever</li> </ul>		<b>Uses</b> temporarily relieves common cold/flu symptoms: <ul style="list-style-type: none"> <li>■ cough due to minor throat and bronchial irritation</li> <li>■ minor aches and pains ■ sore throat ■ headache</li> <li>■ nasal congestion ■ fever</li> </ul>	
<b>Warnings</b> <b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take <ul style="list-style-type: none"> <li>■ more than 4,000 mg of acetaminophen in 24 hours</li> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <b>Allergy alert:</b> 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. ▼		<b>Warnings</b> <b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take <ul style="list-style-type: none"> <li>■ more than 4,000 mg of acetaminophen in 24 hours</li> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <b>Allergy alert:</b> 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. ▼	



<b>Drug Facts (continued)</b>		<b>Drug Facts (continued)</b>	
<b>Sore throat warning:</b> 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.		<b>Sore throat warning:</b> 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.	
<b>Do not use</b> <ul style="list-style-type: none"> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>■ 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.</li> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul>		<b>Do not use</b> <ul style="list-style-type: none"> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>■ 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.</li> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul>	
<b>Ask a doctor before use if you have</b> ■ 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		<b>Ask a doctor before use if you have</b> ■ liver disease ■ diabetes ■ heart disease ■ high blood pressure ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema	
<b>Ask a doctor or pharmacist before use if you are</b> ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin		<b>Ask a doctor or pharmacist before use if you are</b> ■ taking the blood thinning drug warfarin	
<b>When using this product</b> <ul style="list-style-type: none"> <li>■ excitability may occur, especially in children</li> <li>■ marked drowsiness may occur ■ avoid alcoholic drinks</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> </ul>		<b>When using this product do not use more than directed</b>	
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DO NOT USE IF BUSTER UNIT IS BROKEN OR TORN  
 \*\*These products are not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® and Vicks® NyQuil® Cold & Flu.

100% Satisfaction Guarantee!  
 (888) 309-9030

MADE IN CANADA  
 DISTRIBUTED BY  
 DOLGEN CORP. LLC  
 100 MISSION RIDGE  
 GOODLETTSVILLE,  
 TN 37072 USA

**PARENTS:**  
 Learn about team medicine abuse  
 www.StopMedicineAbuse.org

CONVENIENT RECYCLING TAB

58072 VT C1



OPEN OTHER END

AT10



<b>Drug Facts (continued)</b>		<b>Drug Facts (continued)</b>													
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.		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.													
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<b>Other information</b> ■ store at 20-25°C (68-77°F)		<b>Other information</b> ■ store at 20-25°C (68-77°F)													
<b>Inactive ingredients</b> D&C yellow no. 10, edible ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution. *may contain this ingredient		<b>Inactive ingredients</b> edible ink*, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution. *may contain this ingredient													
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## DG HEALTH COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-811	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:559 10-811-72	1 in 1 CARTON; Type 0: Not a Combination Product	06/20/2018	
Quantity of Parts				

Part #	Package Quantity	Total Product Quantity
Part 1	8 BLISTER PACK	16
Part 2	16 BLISTER PACK	32

## Part 1 of 2

### DG HEALTH NIGHT TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

#### Product Information

Route of Administration ORAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

#### Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

#### Product Characteristics

Color	GREEN (clear)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	056
Contains			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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		

## Part 2 of 2

### DG HEALTH DAY TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

## Product Information

Route of Administration ORAL

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

## Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	L994
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
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OTC monograph final	part341		
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OTC monograph final	part341	06/20/2018	

**Labeler** - Dolgencorp, LLC (068331990)

Revised: 12/2019

Dolgencorp, LLC