

**NON DROWSY DAYTIME AND NIGHTTIME COLD AND FLU- acetaminophen,  
dextromethorphan hydrobromide, doxylamine succinate, phenylephrine  
hydrochloride  
DOLGENCORP, INC.**

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**Non Drowsy Daytime and Nighttime Cold and Flu**

***Active ingredients (in each softgel)***

**COLD & FLU NON-DROWSY DAYTIME**

Acetaminophen 325 mg  
Dextromethorphan hydrobromide 10 mg  
Phenylephrine hydrochloride 5 mg

**COLD & FLU NIGHTTIME**

Acetaminophen 325 mg  
Dextromethorphan hydrobromide 15 mg  
Doxylamine succinate 6.25 mg

***Purposes***

**COLD & FLU NON DROWSY DAYTIME**

Pain reliever/fever reducer  
Cough suppressant  
Nasal decongestant

**COLD & FLU NIGHTTIME**

Pain reliever/fever reducer  
Cough suppressant  
Antihistamine

***Uses***

temporarily relieves common cold/flu symptoms:

- fever
- headache
- minor aches and pain
- cough due to minor throat and bronchial irritation
- sore throat
- nasal congestion (**Daytime only**)
- runny nose and sneezing (**Nighttime only**)

***Warnings***

**Liver warning** This product contains acetaminophen. Severe liver damage may occur if you take: ● more than 4 doses in 24 hours, which is the maximum daily amount for this product ● 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
- to make a child sleepy **(Nighttime only)**

### **Ask a doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- liver disease
- trouble urinating due to enlarged prostate gland
- diabetes **(Daytime only)**
- heart disease **(Daytime only)**
- thyroid disease (Daytime only)
- high blood pressure **(Daytime only)**
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema **(Daytime only)**
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema **(Nighttime only)**
- glaucoma **(Nighttime only)**

### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers **(Nighttime only)**

### **When using this product**

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

### **Stop use and ask a doctor if**

- you get nervous, dizzy or sleepless (**Daytime only**)
- pain, nasal congestion, or cough gets worse or lasts more than 7 days (**Daytime only**)
- pain or cough gets worse or lasts more than 7 days (**Nighttime only**)
- 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** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

### **Directions**

Directions (**Daytime only**)

- take only as directed - see Overdose warning
- do not exceed 4 doses per 24 hours

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adults & children 12 years & over	take 2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years of age	do not use

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**● when using other DAYTIME and NIGHTTIME products, carefully read each label to ensure correct dosing**

Directions (**Nighttime only**)

- take only as directed - see Overdose warning
- do not exceed 4 doses per 24 hours

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adults & children 12 years & over	take 2 softgels with water every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years of age	do not use

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**when using other DAYTIME and NIGHTTIME products, carefully read each label to ensure correct dosing**

### **Other information**

- store at room temperature.

## ***Inactive ingredients***

### **DAY RELIEF**

FD&C Red# 40, FD&C Yellow# 6, gelatin, glycerin, polyethylene glycol, myglyol, lecithin, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

### **NIGHT RELIEF**

D&C Yellow# 10, FD&C Blue# 1, gelatin, glycerin, myglyol, lecithin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, polysorb, sorbitol sorbitan, titanium dioxide

## ***Questions or comments?***

**1-888-333-9792**

Distributed by:

**Old East Main Co.**

100 Mission Ridge

Goodlettsville, TN 37072

## **Principal Display Panel**

COMBO PACK

Compare to the active ingredients

in Vicks® DayQuil® & NyQuil®

Cold & Flu LiquiCaps®†

NDC 75712-008-40

non-drowsy daytime

### **Cold & Flu**

Acetaminophen -

Pain Reliever / Fever Reducer

Dextromethorphan HBr -

Cough Suppressant

Phenylephrine HCl - Nasal Decongestant

Relief of:

- Headache • Fever • Sore Throat
- Minor Aches & Pains • Nasal Congestion
- Sinus Pressure • Cough

20 softgels

Nighttime

### **Cold & Flu**

Acetaminophen -

Pain Reliever / Fever Reducer

Dextromethorphan HBr -

Cough Suppressant

Doxylamine Succinate – Antihistamine

Relief of:

- Headache • Fever • Sore Throat
- Minor Aches & Pains • Sneezing
- Runny Nose • Cough

20 softgels

Multi-symptom

40 total softgels



hydrochloride kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75712-010
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75712-010-40	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	04/27/2023	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	20
Part 2	2 BLISTER PACK	20

## Part 1 of 2

### COLD AND FLU NON DROWSY DAY RELIEF

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

## Product Information

<b>Item Code (Source)</b>	NDC:75712-008
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<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	

<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	512;A09
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		10 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 Drug	M012	04/27/2023	

## Part 2 of 2

### COLD AND FLU NIGHT RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Item Code (Source)</b>	NDC:75712-009
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	116;A07
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		10 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 Drug	M012	04/27/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/27/2023	

**Labeler** - DOLGENCORP, INC. (006946172)