# COLD AND HEAD CONGESTION SEVERE- acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated DOLGENCORP, LLC

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#### Dollar General 44-527C-HC

#### Active ingredients (in each caplet)

Acetaminophen 325 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

#### Purpose

Pain reliever/fever reducer Expectorant Nasal decongestant

#### Uses

- for the temporary relief of the following cold symptoms:
  - headache
  - nasal congestion
  - minor aches and pains
  - sinus congestion and pressure
  - sore throat
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces 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:

- blisters
- rash
- skin reddening

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
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- high blood pressure
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- heart disease

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

taking the blood thinning drug warfarin.

## When using this product

## do not exceed recommended dosage.

## Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions

- do not take more than directed
- adults and children 12 years and over
  - take 2 caplets every 4 hours
  - swallow whole do not crush, chew, or dissolve
  - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

## Other information

- each caplet contains: sodium 3 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

#### Inactive ingredients

corn starch, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

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

1-888-309-9030

#### **Principal Display Panel**

**DG**® | health

Compare to active ingredients of Tylenol® COLD + HEAD CONGESTION SEVERE\*

#### Cold & Head Congestion Severe

**Acetaminophen,** Guaifenesin, Phenylephrine HCl Pain Reliever/Fever Reducer, Expectorant, Nasal Decongestant

Relieves:

- Fever/Headache Body aches/Sore throat
- Nasal congestion Mucus/Chest congestion

Pseudoephedrine Free

Non Drowsy

24 Caplets

Actual Caplet Size

#### TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + HEAD CONGESTION SEVERE. 50844 REV0922D52708

DISTRIBUTED BY OLD EAST MAIN CO. 100 MISSION RIDGE GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed! (888) 309-9030



Dollar General 44-527C

## COLD AND HEAD CONGESTION SEVERE

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

<b>Product Infor</b>	mation					
Product Type		HUMAN OTC DRUG	ltem (	ode (Source)	NDC:559	10-927
Route of Admini		ORAL		Code (Source) NDC:55910-927		10 527
Route of Admin	istration	URAL				
Active Ingred	ient/Active	Moiety				
	Ingre	dient Name		Basis of S	trength	Strengt
ACETAMINOPHEN	(UNII: 36209ITI	_9D) (ACETAMINOPHE	EN - UNII:362091			325 mg
GUAIFENESIN (UNI	I: 495W7451VQ	) (GUAIFENES IN - UN	II:495W7451VQ)	GUAIFENES IN		200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)			INE - PHENYLEPHRINE HYDROCHLORIDE		5 mg	
Inactive Ingre	dients					
		Ingredient N	Name		9	Strength
STARCH, CORN (U	NII: 08232NY35	J)				
CROSPOVIDONE,	UNSPECIFIED	(UNII: 2S7830E561)				
MAGNESIUM STEA	RATE (UNII: 70	097M6I30)				
MALTODEXTRIN (L	JNII: 7CVR7L4A2	:D)				
MICROCRYSTALLI		E (UNII: OP1R32D61U	(۲			
POLYETHYLENE G	LYCOL, UNSPI	ECIFIED (UNII: 3WJQ	0SDW1A)			
POLYVINYL ALCO	IOL, UNSPECI	FIED (UNII: 532B59)	990)			
POVIDONE, UNSPI	ECIFIED (UNII:	FZ989GH94E)				
SILICON DIOXIDE	(UNII: ETJ7Z6XE	3U4)				
SODIUM STARCH	GLYCOLATE T	YPE A POTATO (UN	II: 5856J3G2A2)			
STEARIC ACID (UN	II: 4ELV7Z65AP	)				
SUCRALOSE (UNII:	96K6UQ3ZD4)					
TALC (UNII: 7SEV7]	4R1U)					
TITANIUM DIOXID	E (UNII: 15FIX9\	(2JP)				
<b>Product Chara</b>	acteristics					
Color	white		Score		no score	
Shape			19mm			
Flavor	MENT	HOL	Imprint Code	)	44;527	
Contains					, -	
Packaging				Maulating Cta	<b>F4</b>	
# Item Code	Pa	ckage Descript	ion	Marketing Start Date		ting End Date
1 NDC:55910- 927-08	2 in 1 CARTON 12 in 1 BLISTER PACK; Type 0: Not a Combination		08/06/2005			
1	Product	R PACK; Type U: Not	a combination			
		_				
Marketing						

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	08/06/2005	

## Labeler - DOLGENCORP, LLC (068331990)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		832867837	manufacture(55910-927) , pack(55910-927)	

## Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(55910-927)

## Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(55910-927)

Revised: 3/2025

DOLGENCORP, LLC