COLD AND FLU SEVERE DAY TIME / NIGHT TIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, 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.

Dollar General 44-503A473C

Active ingredients (in each caplet) (Daytime Cold & Flu Severe)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Active ingredients (in each caplet) (Nighttime Cold & Flu Severe)

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Antihistamine
Cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - headache
  - sore throat
  - minor aches and pains
  - nasal congestion
  - sinus congestion and pressure ***(Nighttime only)***
  - sneezing and runny nose ***(Nighttime only)***
- help loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive ***(Daytime only)***
- helps clear nasal passages ***(Nighttime only)***
- relieves cough to help you sleep ***(Nighttime only)***
- 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:
- 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
- high blood pressure
- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma ***(Nighttime only)***
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a breathing problem such as emphysema or chronic bronchitis ***(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 exceed recommended dosage**
- excitability may occur, especially in children **(Nighttime only)**
- marked drowsiness may occur **(Nighttime only)**
- avoid alcoholic beverages (**Nighttime only)**
- use caution 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
- nervousness, dizziness, or sleeplessness occur

- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing.

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

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

Inactive ingredients (Daytime only)

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Inactive ingredients (Nighttime only)

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, 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™ ι health

Compare to
active ingredients of
Tylenol® COLD + FLU
SEVERE Day & Night*

Severe • Day Time
Cold & Flu

Acetaminophen,
Dextromethorphan HBr,
Guaifenesin, Phenylephrine HCl

Pain Reliever/Fever Reducer, Cough Suppressant,
Expectorant, Nasal Decongestant

16 Caplets
Actual Caplet Size

Severe • Night Time
Cold & Flu

Acetaminophen,
Chlorpheniramine Maleate,
Dextromethorphan HBr, Phenylephrine HCl

Pain Reliever/Fever Reducer, Antihistamine,
Cough Suppressant, Nasal Decongestant

8 Caplets
Actual Caplet Size

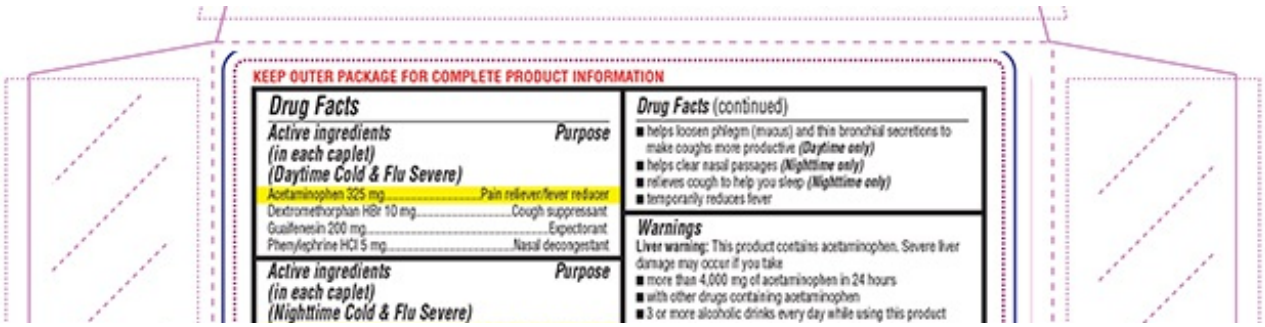
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN
OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + FLU SEVERE Day & Tylenol® COLD + FLU SEVERE Night.

50844 REV0718A50347308

DISTRIBUTED BY
DOLGENCORP, LLC
100 MISSION RIDGE
GOODLETSVILLE, TN 37072

100%
Satisfaction
Guaranteed!
(888)309-9030



Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses ■ temporarily relieves these common cold and flu symptoms: ■ cough ■ headache ■ sore throat ■ nasal congestion ■ minor aches and pains ■ sinus congestion and pressure ***(Nighttime only)*** ■ sneezing and runny nose ***(Nighttime only)***

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

PEEL HERE FOR MORE DRUG FACTS

Severe Cold & Flu

Severe Cold & Flu

B-0315-503A473C-08
REV0718AS0347308

DG™ | health

Compare to active ingredients of Tylenol® COLD + FLU SEVERE Day & Night*

Severe • Day Time Cold & Flu

Acetaminophen,
Dextromethorphan HBr,
Guaifenesin, Phenylephrine HCl

Pain Reliever/Fever Reducer, Cough Suppressant, Expectorant, Nasal Decongestant

16 Caplets
Actual Caplet Size

Severe • Night Time Cold & Flu

Acetaminophen,
Chlorpheniramine Maleate,
Dextromethorphan HBr, Phenylephrine HCl

Pain Reliever/Fever Reducer, Antihistamine, Cough Suppressant, Nasal Decongestant

8 Caplets
Actual Caplet Size

Severe Cold & Flu

No Print / No Varnish Lot no. & Exp. date

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

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A1051

100% Satisfaction Guaranteed!
(888) 309-9030

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5084 REV0718AS034730B

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + FLU SEVERE Day & Night.

ADHESIVE AREA

Drug Facts (continued)

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 ■ high blood pressure ■ liver disease ■ diabetes ■ thyroid disease ■ heart disease ■ glaucoma ***(Nighttime only)*** ■ cough that occurs with too much phlegm (mucus) ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ a breathing problem such as emphysema or chronic bronchitis ***(Nighttime only)***

Ask a doctor or pharmacist before use if you are
■ taking the blood thinning drug warfarin

Drug Facts (continued)

■ taking sedatives or tranquilizers ***(Nighttime only)***

When using this product
■ **do not exceed recommended dosage**
■ excitability may occur, especially in children ***(Nighttime only)***
■ marked drowsiness may occur ***(Nighttime only)***
■ avoid alcoholic beverages ***(Nighttime only)***
■ use caution 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
■ nervousness, dizziness, or sleeplessness occur
■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ new symptoms occur
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present
■ 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.

ADHESIVE AREA

Drug Facts (continued)

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.

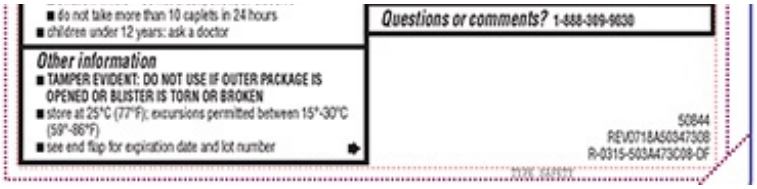
Directions
■ **do not take more than directed**
■ adults and children 12 years and over
■ take 2 caplets every 4 hours
■ swallow whole – do not crush, chew, or dissolve

Drug Facts (continued)

Inactive ingredients (Daytime only)
corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Inactive ingredients (Nighttime only)
corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

ADHESIVE AREA



44-503A473-08

COLD AND FLU SEVERE DAY TIME / NIGHT TIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-573

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55910-573-08	1 in 1 CARTON; Type 0: Not a Combination Product	08/04/2005	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2

COLD AND FLU SEVERE DAY TIME

acetaminophen, dextromethorphan hbr, guaifenesin phenylephrine hcl tablet

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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**

STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;503
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	08/04/2005	

Part 2 of 2

COLD AND FLU SEVERE NIGHT TIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet

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

CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	44;473
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	07/25/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/04/2005	

Labeler - DOLGENCORP, LLC (068331990)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55910-573)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55910-573)

Revised: 4/2019 DOLGENCORP, LLC