

DG HEALTH COLD AND FLU SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
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 Cold & Flu Severe Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- for the temporary relief of the following cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- 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:

- 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

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

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.

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

- **do not take more than directed (see overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none">• 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

Inactive ingredients

acesulfame potassium, carnauba wax, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-309-9030

Principal Display Panel

Compare to the active ingredients of Tylenol® Cold + Flu Severe

Cold & Flu Severe

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

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

Relieves:

Headache • Fever • Cough

Nasal congestion • Sore throat

Chest congestion • Clears out mucus

24 Caplets

Non Drowsy • For Adults

Actual Caplet Size

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

DO NOT USE IF PLASTER UNIT IS BROKEN OR TORN
Important: Read all product information before using.
Keep this box for important information.

DG™ | health

Compare to the
active ingredients
of Tylenol® Cold +
Flu Severe*

Cold & Flu Severe

Acetaminophen, Phenylephrine HCl,
Dextromethorphan HBr, Guaifenesin

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

Relieves:

- Headache • Fever • Cough
- Nasal congestion • Sore throat
- Chest congestion • Clears out mucus

Non Drowsy • For Adults



24 Caplets

Actual Caplet Size

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant

Uses ■ for the temporary relief of the following cold/flu symptoms:
■ minor aches and pains ■ headache ■ sore throat ■ cough
■ nasal congestion ■ helps loosen phlegm (mucus) and thin bronchial
secretions to make coughs more productive ■ temporarily reduces fever

Warnings

Liver warnings: 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

Drug Facts (continued)

Ask a doctor before use if you have ■ liver disease ■ diabetes
■ high blood pressure ■ thyroid disease ■ heart disease
■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema ■ cough that occurs with too much phlegm (mucus)

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. 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 ■ do not take more than directed (see overdose warning)

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

Drug Facts (continued)

Inactive ingredients acetylsalicylic acid, croscarmellose sodium, croscopolone, D & C yellow #10 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Drug Facts (continued)

Questions or comments? 1-888-309-9030

Store at 20°-25°C (68°-77°F).

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Cold + Flu Severe.

23462 VT C9



A 0502

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

100% Satisfaction Guarantee 1-888-309-9030

DG HEALTH COLD AND FLU SEVERE				
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10 -499	
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	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE (UNII: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
Product Characteristics				
Color	YELLOW	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	L234	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:559 10 -499 -62	12 in 1 CARTON	05/27/2014	
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	05/27/2014	

Labeler - Dolgencorp, LLC (068331990)

Revised: 10/2018

Dolgencorp, LLC