

**DG HEALTH COLD MULTI SYMPTOM NITE TIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet, film coated
Dolgenercorp Inc**

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.

Dolgenercorp, LLC Cold Multi-Symptom Drug Facts

Active ingredient (in each caplet)

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 symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- sneezing and runny nose
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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.
- to make a child sleepy

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
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

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

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

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. (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 Liver warning)
-

adults and children 12 years and over	<ul style="list-style-type: none"> • take 2 caplets every 4-6 hours • swallow whole – do not crush, chew or dissolve • do not take more than 12 caplets in 24 hours
children under 12 years	<ul style="list-style-type: none"> • do not use this adult product in children under 12 years of age

Inactive ingredients

acesulfame potassium, FD&C blue no. 1 lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, purified water, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-309-9030

Principal Display Panel

Compare to active ingredients of Tylenol® Cold Multi-Symptom Nighttime

Nite Time

Cold

Multi-Symptom

Pain Reliever/Fever Reducer - Acetaminophen

Nasal Decongestant - Phenylephrine HCl

Cough Suppressant - Dextromethorphan HBr

Antihistamine - Chlorpheniramine Maleate

See New Warnings Information

Instant Cooling Sensation

Cool Ice®

Drug Facts (continued)

Warnings

- temporarily relieves these common cold symptoms: ■ headache ■ minor aches and pains
- sore throat ■ nasal congestion
- cough ■ sneezing and runny nose
- helps clear nasal passages ■ relieves cough by helping you sleep ■ temporarily reduces fever

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 medication (including certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, ask a doctor or pharmacist before taking this product. ■ To make a child sleep.

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

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Drug Facts (continued)

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Nite Time Cold Multi-Symptom

Pain Reliever/Fever Reducer • Acetaminophen
Nasal Decongestant • Phenylephrine HCl
Cough Suppressant • Dextromethorphan HBr
Antihistamine • Chlorpheniramine Maleate

SEE NEW WARNINGS INFORMATION

24 Caplets

INSTANT COOLING SENSATION Cool Ice®

100% Quality Guaranteed
(888) 309-9030

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100% Quality Guaranteed
(888) 309-9030

70030 16854 5

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Cold Multi-Symptom Nighttime.

DISTRIBUTED BY DCL GENCO, LLC
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072 USA

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Cold Multi-Symptom Carton

DG HEALTH COLD MULTI SYMPTOM NITE TIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-014
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

Product Characteristics

Color	BLUE (Light Blue)	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	L393
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-014-62	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/05/2009	

Labeler - Dolgencorp Inc (068331990)