NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- acetaminophen, diphenhydramine hci, phenylephrine hci liquid Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)

Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Diphenhydramine HCI 25 mg

Phenylephrine HCI 10 mg

Purpose

Pain reliever/fever reducer

Antihistamine / cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms
 - cough
 - nasal congestion
 - minor ache and pains
 - sore throat
 - headache
 - runny nose
 - sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

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.
- with any other drug containing diphenhydramine even one used on the skin
- 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.
- for children under 12 years of age

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
- · a breathing problem such as emphysema or chronic bronchitis
- 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

- you are taking the blood thinning drug warfarin
- · you are taking sedatives or tranquilizers

When using this product

- do not use more than directed
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- 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.

Overdose warning: Taking more than the recommended dose (overdose) can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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)
- do not take more than 6 doses in any 24 hours period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL = milliliter
- dose as follows or as directed by a doctor
- adults and children 12 years and older :
 - 20 mL every 4 hours while symptoms last
- children under 12 years of age do not use

Other information

- each 20 mL contains: sodium 12 mg
- store between 20-25°C (68-77F). Do not refrigerate

Inactive ingredients

citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Principal Display Panel

Compare to the active ingredients of Maximum Strength Mucinex® Fast-Max® Night Time Cold & Flu*

Maximum Strength

Fast Acting

Night Time Cold & Flu

Multi-Symptom Relief

Acetaminophen

Diphenhydramine HCI

Phenylephrine HCI

Pain Reliever/Fever Reducer

Antihistamine/Cough Suppressant

Nasal Decongestant

• For ages 12 years and over

FL OZ (mL)

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Night Time Cold & Flu

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

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

Product Label



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PLD-C377D LB003148

Drug Facts Active ingredients Purposes (in each 20 mL) Acetaminophen 650 mg...... ...Pain reliever/fever reducer Diphenhydramine HCl 25 mg. ...Antihistamine/cough suppressant Phenylephrine HCl 10 mg... ...Nasal decongestant Uses temporarily relieves these common cold and flu symptoms ■ cough nasal congestion minor aches and pains sore throat ■ headache ■ runny nose ■ sneezing

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

- temporarily reduces fever
- controls cough to help you get to sleep

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- with any other drug containing diphenhydramine, even one used on the skin

Drug Facts (continued)

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Other information

- each 20 mL contains: sodium 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

PEEL CORNER FOR MORE DRUG FACTS ▲

NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, diphenhydramine hci, phenylephrine hci liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-460	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL		
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL		

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:55910-460-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	03/31/2018		

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 10/2023

Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)