COLD SEVERE CONGESTION- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet tablet
Lil' Drug Store Products, 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.

Cold Severe Congestion

Drug Facts

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Active ingredients

Active ingredients (in each tablet)
Acetaminophen 325 mg

Dextromethorphan HBr 15 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Purpose
Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

Uses
■ for the temporary relief of the following cold/flu symptoms:
■ minor aches and pains

■ headache

■ sore throat
■ nasal congestion

■ cough

■ impulse to cough
■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
■ temporarily reduces fever

Warnings

Liver warning

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

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

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.
A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

Do not use

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.

Ask a doctor before use if you have

Ask a doctor before use if you have
■ liver disease

■ heart disease
■ diabetes

■ thyroid disease

■ high blood pressure
■ trouble urinating due to an enlarged prostate gland
■ cough that occurs with too much phlegm (mucus)

■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are

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

When using this product

When using this product
■ do not exceed recommended dosage

Stop use and ask a doctor if

Stop use and ask a doctor if
■ 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 is accompanied by a fever, rash or persistent headache
■ nervousness, dizziness, or sleeplessness occur.
These could be signs of a serious condition.

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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) Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Directions

adults and children 12 years and over	■ take 2 tablets with water every 6-8 hours as needed ■ do not take more than 8 tablets in 24 hours, or as directed by a doctor
children under 12 years of age	ask a doctor

Other information

Other information

■ store at room temperature 59-86˚ F (15-30˚ C)

Inactive ingredients

Inactive ingredients

maltodextrin, microcrystalline cellulose, povidone, silicon dioxide*, sodium starch glycolate, starch, stearic acid
*may contain

Questions or comments?

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call toll-free **1-877-507-6516 (M-F 8AM-4:30PM CST)**

PDP/Package

Cold

Acetaminophen, Dextromethorphan HBr,

Guaifenesin, Phenylephrine HCl

SEVERE

CONGESTION

Non-Drowsy Relief of

- **Cough, Im[pulse to Cough**
- Nasal Congestion
- Sore Throat
- 50 PACKETS OF 2 TABLETS

[barcode]

3 66715 97187 6

Cold

Acetaminophen, Dextromethorphan HBr,
Guaifenesin, Phenylephrine HCl

SEVERE CONGESTION

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- **Nasal Congestion**
- **Sore Throat**

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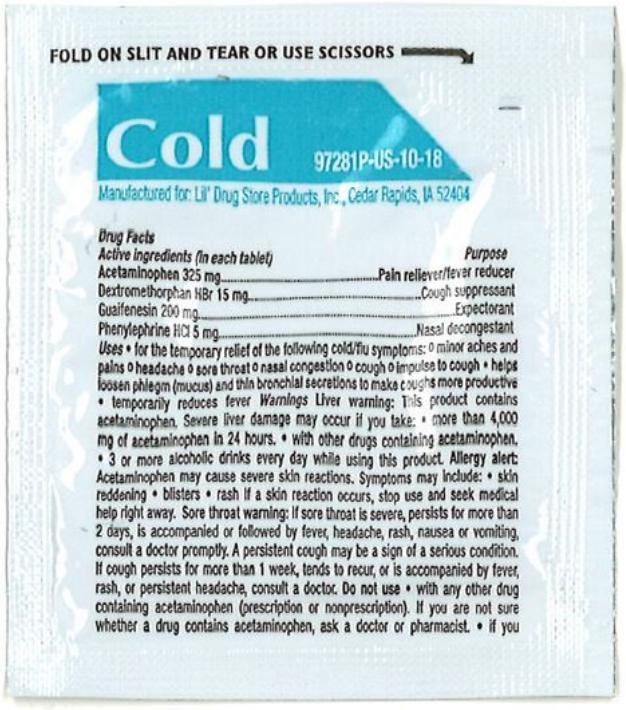

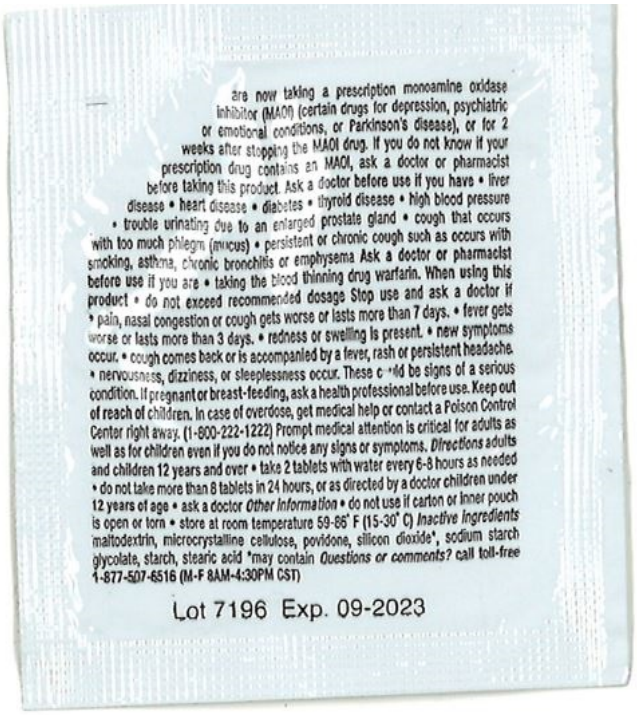

COLD SEVERE CONGESTION

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66715-9818
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics			
Color	white (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	FR;12
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66715-9818-7	50 in 1 BOX, UNIT-DOSE	09/12/2014	
1		2 in 1 POUCH; 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	09/12/2014	

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 8/2022 Lil' Drug Store Products, Inc.