LIL DRUG STORE COLD RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride 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.

Lil' Drug Store ® Cold Relief

Drug Facts

Active ingredients (in each tablet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 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
 - 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

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.

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.

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

taking the blood thinning drug warfarin

When using this product

do not exceed recommended dosage

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

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	■ ask a doctor

Other information

- do not use if carton or inner pouch is open or torn
- store at room temperature 59-86° F (15-30° C)
- avoid excessive heat and humidity
- see bottom panel or pouch for expiration date and lot number

Inactive ingredients

maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments?

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

PRINCIPAL DISPLAY PANEL - 6 Tablet Pouch Carton

QUALITY

GUARANTEED

on

the

Go

PACKS

Cold

Cold

Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl Pain Reliever/Fever Reducer, Cough Suppressant, Expectorant, Nasal Decongestant

Non-Drowsy Relief of

- Cough, Impulse to Cough
- Nasal Congestion
- Sore Throat

SEVERE

CONGESTION

6

Tablets

3 POUCHES, 2 TABLETS PER POUCH

Lil

DrugStore ®



PRINCIPAL DISPLAY PANEL - 20 Tablet Carton - 9828 EZ Paks™

Stores & Travels Easily!

Compare to the active ingredients in

Tylenol ® Cold Head Congestion*
NON-DROWSY FORMULA

Cold Relief

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

SEVERE CONGESTION

Contains 4 Active Medicines:

Acetaminophen... relieves Headache, Sore Throat
Dextromethorphan HBr...relieves Coughing
Guaifenesin...relieves Chest Congestion
Phenylephrine HCl...relieves Nasal Congestion
20 TABLETS

IN 10 POUCHES OF 2 TABLETS Lil'

Drug Store ®



Product manufactured for:

Lif Drug Store Products, Inc. 1201 Continental Place NE Cedar Rapids, IA 52402 www.lildrugstore.com



*This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals Division of McNeil-PPC, Inc. Lii' Drug Store Products, Inc. does not own the Tylenol® Cold Head Congestion trademark.

LOT

EXP

97288C-US-07-12

Drug Facts (continued)

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

- liver disease
- heart disease
- diabetes
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- 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

■ taking the blood thinning drug warfarin

When using this product

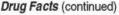
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- cough comes back or is accompanied by a fever, rash or persistent headache
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Directions

adults and children 12 years and over

- take 2 tablets with water every 6-8 hours as needed
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children under 12 years of age ask a doctor

Other Information

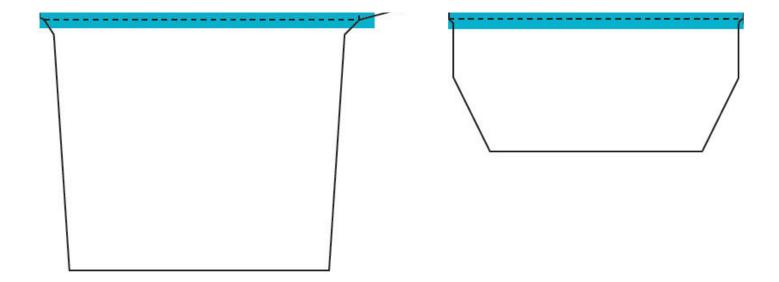
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Inactive Ingredients

croscarmellose sodium*, hypromellose*, maltodextrin*, microcrystalline cellulose, polyethylene glycol*, povidone*, sodium starch glycolate*, starch, stearic acid *may contain

Questions or comments?

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LIL DRUG STORE COLD RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9728
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 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
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR12

Contains

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715- 9728-3	3 in 1 CARTON	07/06/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:66715- 9728-8	10 in 1 CARTON	02/03/2011	02/11/2018
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:66715- 9728-4	30 in 1 CARTON	02/03/2011	02/11/2018
3		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	02/03/2011	

LIL DRUG STORE COLD RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet

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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
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
STARCH, CORN (UNII: O8232NY3SJ)
STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics						
Color	white	Score	no score			
Shape	ROUND	Size	12mm			
Flavor		Imprint Code	AZ;273			
Contains						

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:66715- 9828-3	3 in 1 CARTON	02/03/2011	06/14/2019		
1		2 in 1 POUCH; Type 0: Not a Combination Product				
2	NDC:66715- 9828-8	10 in 1 CARTON	02/03/2011	02/11/2018		
2		2 in 1 POUCH; Type 0: Not a Combination Product				
3	NDC:66715- 9828-4	30 in 1 CARTON	02/03/2011	02/11/2018		
3		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	02/03/2011			

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

Revised: 7/2021 Lil' Drug Store Products, Inc.