# CIRCLE K COLD- 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.

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# Circle K ® Cold

# **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.

# Allergy alert

Acetaminophen may cause severe allergic 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.

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

- 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	<ul> <li>take 2 tablets with water every 6-8 hours as needed</li> <li>do not take more than 8 tablets in 24 hours, or as directed by a doctor</li> </ul>
children under 12 years of age	ask a doctor

## Other information

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

# **Inactive ingredients**

maltodextrin,	, microcrystalline	cellulose,	povidone,	silicon	dioxide 1,	sodium	starch
glycolate, sta	rch, stearic acid						

1 may contain

# **Questions or comments?**

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

Proudly distributed by Circle K Stores Inc.

### PRINCIPAL DISPLAY PANEL - 4 Tablet Pouch Carton

CIRCLE K ®

Cold severe congestion

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

### **ACTUAL SIZE**

Non-Drowsy Relief of

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



congestion

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



# Non-Drowsy Relief of

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



# DO NOT USE IF INNER POUCH OR CARTON IS OPEN OR DAMAGED!

### Drug Facts

Phenylephrine HCI 5 mg

Active ingredients (in each tablet)

Acetaminophen 325 mg.
Dextromethorphan HBr 15 mg.

.Cough suppressant ..Expectorant Nasal decongestant

sore throat

#### Uses

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- minor aches and pains headache nasal congestion
  - cough
- impulse to cough ■ helps loosen phlegm (mucus) and thin bronchial secretions to make
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Allergy alert: Acetaminophen may cause severe allergic reactions Symptoms may include: skin reddening blisters 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,

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LIFT PANEL FOR CONTINUED DRUG FACTS







### Drug Facts (continued)

with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains

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   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

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#### When using this product

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- fever gets worse or lasts more than 3 days
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- new symptoms occur
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### Drug Facts (continued)

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#### Directions

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children under 12 years of age ask a doctor

### Other information

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

#### Inactive ingredients

todextrin, microcrystalline cellulose, povidone, silicon dioxide\*, sodium starch glycolate, starch, stearic acid

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

Product manufactured for: Lil' Drug Store Products, Inc., 9300 Earhart Lane SW Cedar Rapids, IA 52404 www.lildrugstore.com 57282C-US-10-18 Proudly distributed by Circle K Stores Inc.

congestion

CIRCLE



# Principal Display Panel CK Cold, 6ct

TEMPORARY RELIEVES COLD/FLU SYMPTOMS Compare to the active ingredients in **Tylenol® Cold & Flu Severe\*\*** 

### **CIRCLE K**

severe congestion

### cold relief

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

actual size [tablet image]

6 tablets (2 per pouch)



# CIRCLE K COLD

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-5728		
Route of Administration	ORAL				

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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: FZ 989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:66715- 5728-2	2 in 1 CARTON	12/31/2018	11/15/2022		
1		2 in 1 POUCH; Type 0: Not a Combination Product				
2	NDC:66715- 5728-3	3 in 1 CARTON	10/15/2019	09/09/2024		
2		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	11/01/2014	09/09/2024	

# **CIRCLE K COLD**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet

IMAN OTC DRUG	Home Code (Course)	NDC:CC71F FF30
	Item Code (Source)	NDC:66715-5528
RAL		
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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: FZ 989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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	FR;12			
Contains						

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:66715- 5528-3	3 in 1 CARTON	03/26/2021	03/03/2026			
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	03/26/2021	03/03/2026			

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