

**COLD RELIEF MULTI-SYMPTOM- acetaminophen, dextromethorphan hbr,  
phenylephrine hcl tablet, film coated  
Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-470C**

***Active ingredients (in each caplet)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Nasal decongestant

***Uses***

- temporarily relieves these common cold and flu symptoms:
  - minor aches and pains
  - headache
  - nasal congestion
  - cough
  - sore throat
  - sinus congestion and pressure
- temporarily reduces fever
- helps clear nasal passages
- promotes nasal and sinus drainage

***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:

- blisters
- rash
- skin reddening

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.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have**

- liver disease
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

**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**

- 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. Prompt 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**
- adults and children 12 years and over
  - take 2 caplets every 4 hours
  - swallow whole - do not crush, chew, or dissolve
  - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

### ***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

### ***Questions or comments?***

**1-800-426-9391**

### **Principal Display Panel**

**LEADER™**

NDC 70000-0652-1

**Daytime  
Multi-Symptom  
Cold Relief**

**Acetaminophen** | Dextromethorphan HBr | Phenylephrine HCl  
Pain Reliever / Fever Reducer | Cough Suppressant | Nasal Decongestant

**Pseudoephedrine Free**

Temporarily Relieves: Headache, Fever,  
Sore Throat, Cough, Nasal Congestion

**24 CAPLETS with cool blast flavor**

Actual Size

**100% Money  
Back Guarantee**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED  
OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS**

## **ANY SIGNS OF TAMPERING**

### **PARENTS:**

**Learn about teen medicine abuse**

**[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)**

50844 ORG072247008

All LEADER™ Brand

Products Have A

**100%**

**Money Back**

**Guarantee**

Return to place of  
purchase if not satisfied.

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DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com) 1-800-200-6313

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**CIN 5857552 REV. 7/23**

**LEADER**<sup>TM</sup>

NDC 1-0695-00007000

# Daytime Multi-Symptom Cold Relief

**Acetaminophen | Dextromethorphan HBr | Phenylephrine HCl**  
Pain Reliever / Fever Reducer | Cough Suppressant | Nasal Decongestant

Pseudoephedrine Free  
Temporarily Relieves: Headache, Fever, Sore Throat, Cough, Nasal Congestion

**24 CAPLETS** with cool blast flavor



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**100% Money Back Guarantee**

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Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

ALL LEADER<sup>TM</sup> Brand Prescription 100% Money Back Guarantee  
Return to place of purchase for refund.

REV. 7/23  
CIN 5857552  
0 96295 14302 7

8-0025-4700-08  
OR6072247008

**Other information**  
■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BUSTERS IS TORN OR BROKEN  
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)  
■ see end flap for expiration date and lot number

**Drug Facts (continued)**

**Inactive ingredients** com starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

**Questions or comments?** 1-800-426-9391

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**Purpose**  
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**Drug Facts (continued)**  
**Uses**  
temporarily relieves these common cold and flu symptoms:  
■ minor aches and pains  
■ sinus congestion and pressure  
■ sore throat  
■ nasal congestion  
■ headache  
■ cough  
■ temporarily reduces fever

■ promotes nasal and sinus drainage  
■ helps clear nasal passages

**Drug Facts (continued)**  
**Warnings**  
Liver warning: If the 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  
■ or more alcoholic drinks every day while using this product  
**Allergy alert:** Acetaminophen may cause severe skin reactions.  
Symptoms may include:  
■ rash  
■ skin reddening  
■ blisters  
■ sores  
**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 over-the-counter)  
■ 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.  
■ if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have**  
■ thyroid disease  
■ high blood pressure  
■ liver disease  
■ heart disease  
■ diabetes  
■ difficulty in urination due to enlargement of the prostate gland

**Drug Facts (continued)**  
**Directions**  
■ do not take more than directed  
■ adults and children 12 years and over  
■ take 2 caplets every 4 hours  
■ swallow whole - do not crush, chew, or dissolve  
■ do not take more than 10 caplets in 24 hours  
■ children under 12 years: ask a doctor

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Stop use and ask a doctor if**  
■ new symptoms occur  
■ fever gets worse or lasts more than 3 days  
■ redness or swelling is present  
■ 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.

**When using this product do not exceed recommended dosage.**

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

**Stop use and ask a doctor if**  
■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema  
■ cough that occurs with too much phlegm (mucus)

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

**Stop use and ask a doctor if**  
■ new symptoms 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  
■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

no print / no varnish area  
lot no. & exp. date

50844 OR6072247008  
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DUBLIN, OHIO 43017  
[www.ryleader.com](http://www.ryleader.com) 1-800-200-6313

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BUSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

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Leader 44-470

**COLD RELIEF MULTI-SYMPOTM**  
acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0652
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	44;470
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0652-1	2 in 1 CARTON	10/25/2023	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	10/25/2023	

**Labeler** - Cardinal Health 110, LLC. DBA Leader (063997360)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0652) , pack(70000-0652, 70000-0652)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0652, 70000-0652)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0652)

Revised: 10/2025

Cardinal Health 110, LLC. DBA Leader