

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

Leader 44-470

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

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

All LEADER™ Brand

Products Have A

Money Back

100%

Guarantee

Return to place of
purchase if not satisfied.

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313

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OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS
ANY SIGNS OF TAMPERING

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LEADERTM

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



100% Money Back Guarantee

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Learn about teen medicine abuse
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Return to place of purchase for refund.

REV. 7/23
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0 96295 14302 7

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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

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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 using this product
Allergy alert: Acetaminophen may cause severe skin reactions.
Symptoms may include:
■ rash
■ skin reddening
■ blisters
■ itching
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.
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■ 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
■ heart disease
■ diabetes
■ difficulty in urination due to enlargement of the prostate gland

Drug Facts (continued)

Warnings
■ 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
■ new symptoms occur
■ fever gets worse or lasts more than 3 days
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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.

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

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www.ryleader.com 1-800-200-6513

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Leader 44-470

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

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

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

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: 10/2023

Cardinal Health 110, LLC. DBA Leader