

ALLERGY MULTI-SYMPTOM- acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet, film coated
Cardinal Health 110, LLC. DBA Leader

Leader 44-455C-AMS

Active ingredients (in each caplet)

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever
Antihistamine
Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 - headache
 - nasal congestion
 - runny nose and sneezing
 - minor aches and pains
 - sinus congestion and pressure
- temporarily relieves these additional symptoms of hay fever:
 - itchy, watery eyes
 - itching of the nose or throat
- helps clear nasal passages
- helps decongest sinus openings and passages

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.

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

- difficulty in urination due to enlargement of the prostate gland
- high blood pressure
- a breathing problem such as emphysema or chronic bronchitis
- heart disease
- thyroid disease
- diabetes
- liver disease
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- drowsiness may occur

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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 accidental overdose, get medical help or contact a Poison Control Center (1-

800-222-1222) 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°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

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

Questions or comments?

1-800-426-9391

Principal Display Panel

LEADER™

NDC 70000-0211-1

Allergy

Multi-Symptom

Acetaminophen | Pain Reliever

Chlorpheniramine Maleate | Antihistamine

Phenylephrine HCl | Nasal Decongestant

Relief of:

Headache, Sinus Pressure,
Nasal Congestion, Runny Nose,
Sneezing, Itchy, Watery Eyes

Pseudoephedrine Free

24 CAPLETS

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**

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LEADER, and the Leader LOGO are trademarks
or registered trademarks of Cardinal Health.

100%
Money Back
Guarantee

Return to place of purchase
if not satisfied.

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979



NDC 70000-0210-1

Allergy Multi-Symptom

Acetaminophen | Pain Reliever Chlorpheniramine Maleate | Antihistamine Phenylephrine HCl | Nasal Decongestant

Relief of:
Headache, Sinus Pressure,
Nasal Congestion, Runny Nose,
Sneezing, Itchy, Watery Eyes

CIN 5305099 REV. 1/19



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HEALTH

1-200-6315

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients (in each caplet)
Acetaminophen 325 mg, Pain reliever
Chlorpheniramine maleate 2 mg, Antihistamine
Phenylephrine HCl 5 mg, Nasal decongestant

Drug Facts (continued)

Temporarily relieves these additional symptoms of hay fever: itchy, watery eyes
helps clear nasal passages
helps decongest sinus openings and passages

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 or 3 or more alcoholic drinks every day while using this product.
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: hives, rash, skin reddening, blisters. If a skin reaction occurs, stop use and seek medical help right away.

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 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
difficulty in urination due to enlargement of the prostate gland ■ high blood pressure

Drug Facts (continued)

Uses ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies: headache ■ nasal congestion ■ runny nose and sneezing ■ minor aches and pains ■ sinus congestion and pressure

Drug Facts (continued)

temporarily relieves these additional symptoms of chronic bronchitis ■ heart disease ■ thyroid disease ■ diabetes ■ liver disease ■ glaucoma

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

When using this product
do not exceed recommended dosage ■ excitability may occur, especially in children ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic beverages or use caution when driving a motor vehicle or operating machinery ■ drowsiness may occur

Stop use and ask a doctor if
nervousness, dizziness, or sleeplessness occur ■ pain or nasal congestion gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present

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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 ■ children under 12 years: ask a doctor

Drug Facts (continued)
Questions or comments?
1-800-426-9391



Return to place of purchase if not satisfied.

TAMPER EVIDENT PACKAGE UNIT IS T ANY

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no pr lot no



Leader 44-455C

ALLERGY MULTI-SYMP TOM

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0211
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
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)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
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;455
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0211-1	2 in 1 CARTON	06/28/2005	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/28/2005	

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0211)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0211) , pack(70000-0211)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0211)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0211)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0211)