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 HCI | Nasal Decongestant

Relief of:

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

Pseudoephedrine Free

24 CAPLETS

100% Money Back Guarantee

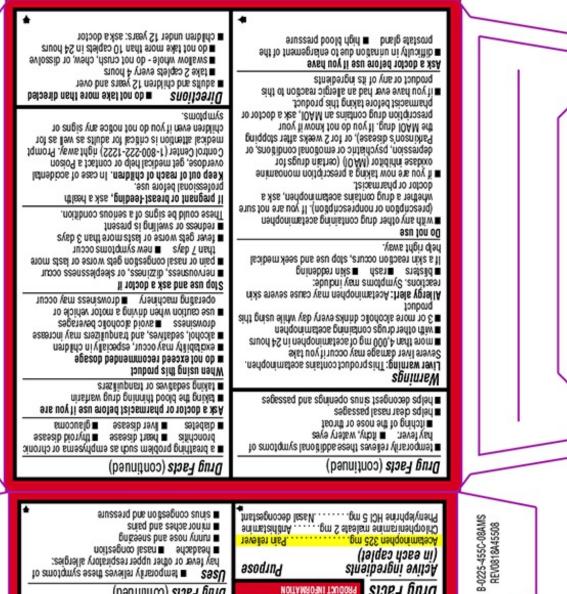
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

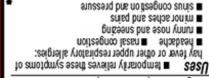
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100% Money Back Guarantee

Return to place of purchase if not satisfied.

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Drug Facts (continued)

Purpose

Active ingredients

PRODUCT INFORMATION KEEP OUTER PACKAGE FOR COMPLETE

Drug Facts

LEADER?

NDC 70000-0211-1

Allergy

Multi-Symptom

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

Relief of:

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

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> Return to place of purchas if not satisfied

Drug Facts (continued

PACKAGE UNIT IS I ANY no pri TAMPER





Leader 44-455C

ALLERGY MULTI-SYMPTOM

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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, 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: 4ELV7Z 65AP)	
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
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)

Revised: 8/2023 Cardinal Health 110, LLC. DBA Leader