

ALLERGY MULTI-SYMPTOM- acetaminophen, chlorpheniramine maleate and phenylephrine hcl tablet, film coated

Family Dollar Services 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.

Family Wellness 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
- glaucoma
- high blood pressure
- a breathing problem such as emphysema or chronic bronchitis
- heart disease
- thyroid disease
- diabetes
- liver disease

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

NDC 55319-455-08

**FAMILY
wellness™**

**Allergy
Multi-Symptom**

**Acetaminophen, Chlorpheniramine Maleate,
Phenylephrine HCl**

Pain Reliever/Antihistamine/Nasal Decongestant

Relief of:

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

24 COOL BLAST FLAVOR
CAPLETS

ACTUAL SIZE

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

50844 REV0818E45508

DISTRIBUTED BY: MIDWOOD BRANDS, LLC
10611 MONROE RD., MATTHEWS, NC 28105

NOT 100% SATISFIED?

Return package and unused product within
30 days to any Family Dollar store for a
refund (with receipt) or exchange.

No print/No varnish
Lot & Exp date

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS
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50944 REV0918E45508

Drug Facts (continued)
Questions or comments?

Allergy Multi-Symptom

Acetaminophen, Chlorpheniramine Maleate,
Phenylephrine HCl

Pain Reliever/Antihistamine/Nasal Decongestant

Relief of:

- Headache • Sinus Pressure
- Nasal Congestion
- Runny Nose • Sneezing



FAMILY
wellness™

NDC 55319-455-08

KEEP OUTER PACKAGE FOR COMPLETE
PRODUCT INFORMATION

Drug Facts

Active ingredients

Acetaminophen 325 mg.....Pain reliever

Chlorpheniramine maleate 2 mg.....Antihistamine

Phenylephrine HCl 5 mg.....Nasal decongestant *

Purpose

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)

■ a breathing problem such as emphysema or chronic
bronchitis ■ heart disease ■ thyroid disease

■ diabetes ■ liver disease

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

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These could be signs of a serious condition.

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Keep out of reach of children. In case of accidental

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medical attention is critical for adults as well as for

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Drug Facts (continued)

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itching of the nose or throat

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Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

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■ 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:

■ hives ■ rash ■ skin reddening

■ blisters ■ skin reaction occurs, stop use and seek medical

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■ with any other drug containing acetaminophen

(prescription or nonprescription). If you are not sure

whether a drug contains acetaminophen, ask a

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■ if you are now taking a prescription monoamine

oxidase inhibitor (MAOI) (certain drugs for

depression, psychiatric or emotional conditions, or

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

■ rhinitis ■ high blood pressure

SKU 0916918



ED BY: MIDWOOD BRANDS, LLC
ROE RD., MATTHEWS, NC 28105

SATISFIED?
age and unused product within
ny Family Dollar store for a
(receipt) or exchange.

B-0500-455C-08AMRR
REV0818E45508



Family Wellness 44-455C

ALLERGY MULTI-SYMPTOM

acetaminophen, chlorpheniramine maleate and phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-455
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
CROSCAPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor	MINT	Imprint Code	44;455
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-455-08	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 FINAL	part341	06/28/2005	

Labeler - Family Dollar Services Inc (024472631)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55319-455)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55319-455)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55319-455)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(55319-455)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(55319-455)