RAPID RELEASE MULTI-SYMPTOM ALLERGY RELIEF- acetaminophen, phenylephrine hcl, chlorpheniramine maleate capsule, gelatin coated Wal-Mart Stores 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.

Equate 44-559 Delisted

Active ingredients (in each gelcap)

Acetaminophen 325 mg Chlorpheniramine maleate 2 mg Phenylepherine HCl 5 mg

Purpose

Pain reliever Antihistamine Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 - sinus congestion and pressure
 - nasal congestion
 - runny nose and sneezing
 - headache
 - minor aches and pains
- temporarily relieves these additional symptoms of hay fever
 - itching of the nose or throat
 - 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 12 gelcaps in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 taking the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

liver disease

- diabetes
- heart disease
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- 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 drinks
- be careful 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
- new symptoms occur
- 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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick 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 (see overdose warning)
- adults and children 12 years and over
 - take 2 gelcaps every 4 hours
 - do not take more than 12 gelcaps in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- see end flap for expiration date and lot number
- store at 25°C (77°); excursions permitted between 15° to 30°C (59°-86°F)

contains FD&C yellow #5 (tartrazine) as a color additive

Inactive ingredients

croscarmellose sodium, crospovidone, FD&C red #3, FD&C red #40, FD&C yellow #5, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, silica gel, stearic acid, titanium dioxide

Questions?

1-888-287-1915

Principal display panel

NDC 49035-559-08

equate®

Compare to Tylenol® Allergy Multi-Symptom Active Ingredients*

Rapid Release **Multi-Symptom**

Allergy Relief

Pain reliever, Nasal decongestant, Antihistamine

Contains 3 medicines

- Headache **Acetaminophen**
- Sinus pressure/Nasal Congestion Phenylephrine HCl
- Runny nose/Sneezing Itchy, Watery eyes - Chlorpheniramine maleate

Pseudoephedrine Free

24

GELCAPS

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716 ©Wal-Mart Stores, Inc.

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Allergy Multi-Symptom.

50844 REV0812A55908

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

bovidone, pregelatinized starch, propylene glycol, uncunculargiilus cainnioas' boikarukisus đikcor' red, iron axide yellow, magnesium stearate, cellulose, hypromellose, iron axide black, iron axide yellow #5, FD&C yellow #6, gelatin, hydroxypropył

Inactive ingredients croscarmellose sodium, 👞

- contains FD&C Yellovy #5 (tartrazine) as a color 12,-30,C (23,-89,E)
- store at 25°C (77°F); excursions permitted between

Drug Facts (continued)

crospovidone, FD&C red #3, FD&C red #40, FD&C Drug Facts (continued)

■ see end flap for expiration date and lot number потьет іптогтатіоп

(overdose) and may cause liver damage provide more than the recommended dose broduct in children under 12 years of age; this will

- children under 12 years: do not use this adult ■ do not take more than 12 gelcaps in 24 hours ■ pake 2 gelcaps every 4 hours
 - adults and children 12 years and over (see overdose warning)

DIRECTIONS - do not take more than directed

nodice any signs or symptoms. squits as well as for children even if you do not right away. Quick medical attention is critical for contact a Poison Control Center (1-800-222-1222) damage. In case of overdose, get medical help or recommended dose (overdose) may cause liver children. Overdose warning: Taking more than the biolessional before use. Keep out of reach of If pregnant or breast-feeding, ask a health

These could be signs of a serious condition.

- redness or swelling is present ■ lever gets vvorse or lasts more than 3 days
- gusu y qsiks uew skubtours occnr ■ bøju ot usesj couðestjou deta worse or issta more
- nervousness, dizziness, or sleeplessness occur

Stop use and ask a doctor if

oberating machinery a drowsiness may occur De careful when driving a motor vehicle or

- svojq sjcopojic guuks SSanisworb sicohol, sedatives, and tranquilizers may increase
 - excitability may occur, especially in children
 - m do not exceed recommended dosage When using this product

Drug Facts (continued)

siazijinbueig jo savgepas buwej mishew gurb grinning boold art gnistst Ask a doctor or pharmacist before use if you are

- chronic bronchibs s preathing problem such as emphysema or
- trouble uninating due to an enlarged prostate gland
 - aspasio pioulun ... ■ µiðµ pjoog bussanus Inver disease ■ disbetes ■ heart disease

Ask a doctor before use if you have

or pharmacist before taking this product. prescription drug contains an MAOI, ask a doctor the MAOI drug. If you do not know if your Parkinson's disease), or for 2 weeks after stopping depression, psychiatric or emotional conditions, or oxidase inhibitor (MAOI) (certain drugs for

 If you are now taking a prescription monoamine doctor or pharmacist. whether a drug contains acetaminophen, ask a (brescription or nonprescription). If you are not sure with any other drug containing acetaminophen

osu jou og

guis broduct

- 3 or more alcoholic drinks every day while using with other drugs containing acetaminophen maximum daily amount
- more than 12 gelcaps in 24 hours, which is the Severe liver damage may occur if you take: Liver warning: This product contains acetaminophen Warnings

- pejbe qecoudest siuns obeujude suq baseades ■ µejbe cjest usesj basesôse
 - ifchy, watery eyes
- usy tever: a itching of the nose or throat temporarily relieves these additional symptoms of

Drug Facts (continued)

Satisfaction guaranteed - for questions or comments please call 1-888-287-1915.

ufactured or distributed by McNeil Consumer registered trademark Tylenol* Altergy 50844 REV0812A55908 Bentomille, AR 72716 Distributed by: Wal-Mart Stores, Inc., Br © Wal-Mart Stares, Inc. "This product is not manufactured or dis owner of the

ŧ∞

ø

 sujed pue sauge Joujilu Bussal congestion ■ runny nose and sneezing siuns coudespou sug buessnue

usy tever or other upper respiratory altergies: USES - temporarily relieves these symptoms of

Drug Facts (continued)

Phenylephrine HCl 5 mg. Masal decongestant Chlorpheniramine maleate 2 mg.....Antihistamine Active ingredients (in each gelcap) Purpose

RODUCT INFORMATION RETAIN CARTON FOR COMPLETE Drug Facts

NDC 49075-559-08



Compare to Tylenol® Allergy **Multi-Symptom** Active Ingredients*

Rapid Release

Multi-Symptom **Allergy Relief**

Pain reliever, Nasal decongestant, Antihistamine

B-2203-559-08 REV0812A55908

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

Drug

Facts

silica gel continued

uestions?

1-888-287-1915

equate[®]



RAPID RELEASE MULTI-SYMPTOM ALLERGY RELIEF

acetaminophen, phenylephrine hcl, chlorpheniramine maleate capsule, gelatin coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-559	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERROSOFERRIC OXIDE (UNII: XM0 M87F357)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
GELATIN (UNII: 2G86QN327L)				

Product Characteristics			
Color	YELLOW (red with grey band)	Score	no score
Shape	CAPSULE	Size	19 mm
Flavor		Imprint Code	L;9
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-559- 08	1 in 1 CARTON		
1		24 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	03/17/2008	

Labeler - Wal-Mart Stores Inc (051957769)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(49035-559)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	MANUFACTURE(49035-559)	

Revised: 10/2015 Wal-Mart Stores Inc