ALLERGY RELIEF MULTI-SYMPTOM- acetaminophen, phenylephrine hcl, chlorpheniramine maleate tablet
DOLGENCORP, LLC

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.

Rexall 44-559-Delisted

Active ingredients (in each gelcap)

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:
  - runny nose and sneezing
  - nasal congestion
  - minor aches and pains
  - headache
  - 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 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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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
- a breathing problem such as emphysema or chronic bronchitis
- high blood pressure
- heart disease
- diabetes
- liver disease
- difficulty in urination due to enlargement of the prostate gland
- glaucoma
- thyroid 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
- may cause drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

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 gelcaps every 4 hours
  - do not take more than 10 gelcaps in 24 hours
- children under 12 years: ask a doctor

Other information

- contains FD&C Yellow #5 (tartrazine) as a color additive
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- avoid high humidity
- see end flap for expiration date and lot number
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)

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

Principal display panel

Since 1903
Rexall®

RAPID RELEASE
Multi-Symptom
Allergy Relief
Acetaminophen 325 mg,
Chlorpheniramine maleate 2 mg,
Phenylephrine HCl 5 mg

• Pain Reliever
• Antihistamine
• Nasal Decongestant

24
Gelcaps

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 REV0216B55908

Visit us at: Rexall.com or call 1-866-4-REXALL

MANUFACTURED FOR DOLGENCORP, LLC
100 MISSION RIDGE GOODLETTSVILLE TN 37072 USA

Since 1903

Rexall®

RAPID RELEASE

Multi-Symptom Allergy Relief

Acetaminophen 325 mg,
Chlorpheniramine maleate 2 mg,
Phenylephrine HCl 5 mg

- Pain Reliever
- Antihistamine
- Nasal Decongestant

Actual Size

24 Gelcaps

A0670

3 50844 55908 1

50844 REV0216855908

Visit us at: Rexall.com or call 1-866-4-REXALL

MANUFACTURED FOR DOLGENCORP, LLC
100 MISSION RIDGE, GOODLETTSVILLE, TN 37072 USA

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

NO PRINT/NO VARNISH
LOT & EXP DATE

Drug Facts (continued)

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

B-0315-559-08-REX
REV0216855908

Drug Facts (continued)

Other information ■ contains FD&C Yellow #5 (tartrazine) as a color additive
■ **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
■ avoid high humidity
■ see end flap for expiration date and lot number

Drug Facts (continued)

■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients croscarmellose sodium, crospovidone, FD&C red #3, FD&C red #40, FD&C yellow #5, FD&C yellow #6, gelatin, hydroxypropyl

■ rctning 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 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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
■ skin reddening ■ blisters ■ rash

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

■ a breathing problem such as emphysema or chronic bronchitis ■ high blood pressure

prostate gland ■ glaucoma ■ thyroid 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 ■ may cause drowsiness
■ use caution when driving a motor vehicle or operating machinery
■ avoid alcoholic beverages

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 gelcaps every 4 hours
■ do not take more than 10 gelcaps in 24 hours
■ children under 12 years: ask a doctor

Rexall 44-559

ALLERGY RELIEF MULTI-SYMPTOM

acetaminophen, phenylephrine hcl, chlorpheniramine maleate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-955
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHELLAC (UNII: 46N107B71O)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	RED, YELLOW	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	L;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-955-08	2 in 1 CARTON	03/17/2008	06/25/2021
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	03/17/2008	06/25/2021

Labeler - DOLGENCORP, LLC (068331990)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55910-955)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55910-955)

Revised: 12/2019 DOLGENCORP, LLC