COLD/FLU MULTI-SYMPTOM RELIEF DAYTIME/NIGHTTIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl
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 44-559-560 Delisted

Active ingredients (in each gelcap) (Daytime Cold Multi-Symptom)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Active ingredients (in each gelcap) (Nighttime Flu Relief)

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Antihistamine
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- headache
- nasal congestion
- sore throat **(Daytime only)**
- cough **(Daytime only)**
- minor aches and pains
- sinus congestion and pressure
- runny nose and sneezing **(Nighttime only)**
- helps clear nasal passages

- promotes nasal and sinus drainage
- temporarily reduces fever
- temporarily relieves these additional symptoms of hay fever or other upper respiratory allergies: **(Nighttime only)**
  - itching of the nose or throat **(Nighttime only)**
  - itchy, watery eyes **(Nighttime only)**

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache,
rash, nausea, or vomiting, consult a doctor promptly. **(Daytime only)**

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
- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma ***(Nighttime only)***
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus) ***(Daytime only)***
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema ***(Daytime only)***

- a breathing problem such as emphysema or chronic bronchitis ***(Nighttime only)***

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ***(Nighttime only)***

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

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition. ***(Daytime only)***

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.

Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time

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 ***(Nighttime only)***
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)

- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients (Daytime only)

croscarmellose sodium, crospovidone, D&C red #28, FD&C blue #1, FD&C red #40, 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, silicon dioxide, stearic acid, titanium dioxide

Inactive ingredients (Nighttime only)

corn starch, 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, propylene glycol, shellac glaze, silicon dioxide, stearic acid, titanium dioxide

Principal display panel

Since 1903
Rexall®

NON-DROWSY
RAPID RELEASE

RAPID RELEASE

Cold/Flu Multi-Symptom Relief

Daytime
ACETAMINOPHEN 325 mg,
DEXTROMETHORPHAN HBr 10 mg,
PHENYLEPHRINE HCl 5 mg

- pain reliever/fever reducer
- cough suppressant
- nasal decongestant

Actual Size

Nighttime
ACETAMINOPHEN 325 mg,
CHLORPHENIRAMINE MALEATE 2 mg,
PHENYLEPHRINE HCl 5 mg

- pain reliever/fever reducer
- antihistamine
- nasal decongestant

Actual Size

PSEUDOEPHEDRINE FREE

12 DAYTIME
GELCAPS

12 NIGHTTIME
GELCAPS

24 TOTAL GELCAPS

COMBO PACK

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS

OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Visit us at: Rexall.com or call 1-866-4-REXALL
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100 MISSION RIDGE, GOODLETTSVILLE, TN 37072 USA

50844 REV0718D55956008

product

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

If a skin reaction occurs, stop use and seek medical help right away.

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Ask a doctor before use if you have
- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma ***(Nighttime only)***
- high blood pressure
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Drug Facts (continued)

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Directions ■ do not take more than directed
- adults and children 12 years and over
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Drug Facts (continued)
- **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)
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- see end flap for expiration date and lot number

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Inactive ingredients (Nighttime only)
corn starch, croscarmellose sodium, crospovidone,

B-0315-559/560-08
REV0718D55956008

Since 1903 Rexall®

Cold/Flu Multi-Symptom Relief

Daytime

NON-DROWSY

RAPID RELEASE

Nighttime

RAPID RELEASE

COMBO PACK 24 TOTAL GELCAPS

12 DAYTIME GELCAPS

12 NIGHTTIME GELCAPS

ACETAMINOPHEN 325 mg,
DEXTROMETHORPHAN HBr 10 mg,
PHENYLEPHRINE HCl 5 mg

- pain reliever/fever reducer
- cough suppressant
- nasal decongestant

Actual Size

ACETAMINOPHEN 325 mg,
CHLORPHENIRAMINE MALEATE 2 mg*,
PHENYLEPHRINE HCl 5 mg

- pain reliever/fever reducer
- antihistamine
- nasal decongestant

Actual Size

PSEUDOEPHEDRINE FREE

12 DAYTIME GELCAPS

COMBO PACK 24 TOTAL GELCAPS

12 NIGHTTIME GELCAPS

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Cold/Flu Multi-Symptom Relief

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Nighttime

RAPID RELEASE

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Drug Facts (continued)

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, propylene glycol, shellac glaze, silicon dioxide, stearic acid, titanium dioxide

50844 REV0718D55956008

Since 1903 Rexall® is a registered trademark of Rexall Sundown, Inc.

NO PRINT / NO VARNISH LOT NO. & EXP. DATE

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

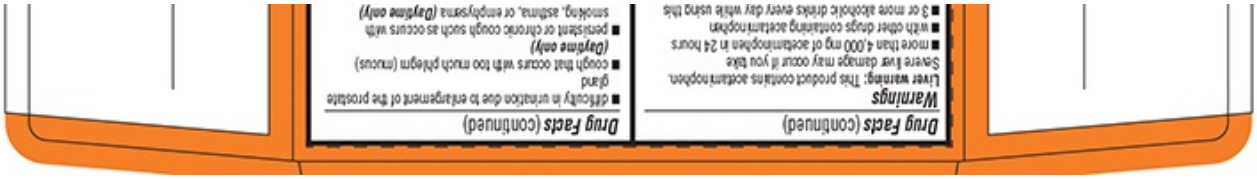
Drug Facts

Active ingredients (in each gelcap) (Daytime Cold Multi-Symptom)	*Purpose*
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each gelcap) (Nighttime Flu Relief)	*Purpose*
Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Drug Facts (continued)

Uses ■ temporarily relieves these common cold and flu symptoms:
- headache
- nasal congestion
- sore throat ***(Daytime only)***
- cough ***(Daytime only)***
- minor aches and pains
- sinus congestion and pressure
- runny nose and sneezing ***(Nighttime only)***
- helps clear nasal passages
- promotes nasal and sinus drainage
- temporarily reduces fever
- temporarily relieves these additional symptoms of hay fever or other upper respiratory allergies: ***(Nighttime only)***
  - itching of the nose or throat ***(Nighttime only)***
  - itchy, watery eyes ***(Nighttime only)***



Rexall 44-556560

COLD/FLU MULTI-SYMPTOM RELIEF DAYTIME/NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-956

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55910-956-08	1 in 1 CARTON; Type 0: Not a Combination Product	03/29/2008	03/17/2023

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2

COLD/FLU MULTI-SYMPTOM RELIEF DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	red, purple	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	L;0
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	03/29/2008	

Part 2 of 2

COLD/FLU MULTI-SYMPTOM RELIEF NIGHTTIME

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet, coated

Product Information

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)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	yellow, red	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	L;9
Contains			

Packaging

	Item		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	03/27/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/29/2008	03/17/2023

Labeler - DOLGENCORP, LLC (068331990)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(55910-956)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(55910-956)

Revised: 7/2022 DOLGENCORP, LLC