

**COLD AND FLU SEVERE, DAYTIME, NIGHTTIME- acetaminophen,
chlorpheniramine maleate, dextromethorphan hbr, guaifenesin,
phenylephrine hcl
Rite Aid Corporation**

Rite Aid 44-503A473C

Active ingredients (in each caplet) (Daytime Cold & Flu Severe)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Active ingredients (in each caplet) (Nighttime Cold & Flu Severe)

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Antihistamine
Cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough
 - headache
 - sore throat
 - nasal congestion
 - minor aches and pains
 - sinus congestion and pressure
 - sneezing and runny nose (***Nighttime only***)
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive (***Daytime only***)

- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

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:

- 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.

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

- high blood pressure
- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma **(Nighttime only)**
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- 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**)
- marked 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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. 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 overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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 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

- **each caplet contains:** sodium 3 mg
- **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 (Daytime only)

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Inactive ingredients (Nighttime only)

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, 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 11822-5034-8

Compare to the active ingredients in

Tylenol® COLD + FLU SEVERE Day & Tylenol® COLD + FLU SEVERE Night*

COLD & FLU SEVERE

DAYTIME	NIGHTTIME
ACETAMINOPHEN	ACETAMINOPHEN
DEXTROMETHORPHAN HBr	CHLORPHENIRAMINE MALEATE
GUAIFENESIN	DEXTROMETHORPHAN HBr
PHENYLEPHRINE HCl	PHENYLEPHRINE HCl
PAIN RELIEVER/FEVER REDUCER	PAIN RELIEVER/FEVER REDUCER
COUGH SUPPRESSANT • EXPECTORANT	ANTIHISTAMINE • COUGH SUPPRESSANT
NASAL DECONGESTANT	NASAL DECONGESTANT
Fever, Headache, Sore Throat, Nasal Congestion, Cough, Mucus, Chest Congestion	Fever, Headache, Sore Throat, Runny Nose, Cough, Nasal Congestion
ACTUAL SIZE	ACTUAL SIZE

PSEUDOEPHEDRINE FREE

16

DAYTIME

CAPLETS

8

NIGHTTIME

CAPLETS

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

ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + FLU SEVERE Day & Tylenol® COLD + FLU SEVERE Night.

SATISFACTION GUARANTEE

If you're not satisfied, we'll
happily refund your money.

DISTRIBUTED BY: RITE AID,
200 NEWBERRY COMMONS
ETTERS, PA 17319 **www.riteaid.com**

50844 REV0922A50347308

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredients
(in each caplet)
(Daytime Cold & Flu Severe)

Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Purpose

Active ingredients
(in each caplet)
(Nighttime Cold & Flu Severe)

Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Purpose

Uses ■ temporarily relieves these common cold and flu symptoms: ■ cough ■ headache ■ sore throat ■ nasal congestion ■ minor aches and pains ■ sinus congestion and pressure ■ sneezing and runny nose (Nighttime only)

Drug Facts (continued)

■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive (Daytime only)
■ helps clear nasal passages
■ relieves cough to help you sleep
■ temporarily reduces fever

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: ■ 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.

Do not use

■ with any other drug containing acetaminophen (prescription or

TYPE SAFETY

PEEL HERE FOR MORE DRUG FACTS

COLD & FLU SEVERE



DAYTIME



NIGHTTIME

B-1702503A4730083
REV0922A503A47308

NDC 11822-5034-8

Compare to the active ingredients in
Tylenol® COLD + FLU SEVERE Day & Tylenol® COLD + FLU SEVERE Night*

COLD & FLU SEVERE



DAYTIME



NIGHTTIME

ACETAMINOPHEN
DEXTROMETHORPHAN HBr
GUAIFENESIN
PHENYLEPHRINE HCl
PAIN RELIEVER/FEVER REDUCER
COUGH SUPPRESSANT • EXPECTORANT
NASAL DECONGESTANT
Fever, Headache, Sore Throat,
Nasal Congestion, Cough,
Mucus, Chest Congestion

ACTUAL SIZE



ACETAMINOPHEN
CHLORPHENIRAMINE MALEATE
DEXTROMETHORPHAN HBr
PHENYLEPHRINE HCl
PAIN RELIEVER/FEVER REDUCER
ANTIHISTAMINE • COUGH SUPPRESSANT
NASAL DECONGESTANT
Fever, Headache, Sore Throat,
Runny Nose, Cough,
Nasal Congestion

ACTUAL SIZE

16
DAYTIME
CAPLETS

8
NIGHTTIME
CAPLETS

PSEUDOEPHEDRINE FREE

NO PRINT AREA
LOT & EXP. DATE

TAMPER EVIDENT: DO NOT USE IF
PACKAGE IS OPENED OR IF BLISTERS
OR BUBBLES ARE VISIBLE
AND BLENDS OF TAMPERING



www.StephensHealthcare.org
PARENTS:
Learn about your medicine choice

REV0922A503A47308

DISTRIBUTED BY: RTE AID,
200 NEWBERRY COMMONS
EASTERS, PA 17319 www.rteaaid.com

SATISFACTION
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Drug Facts (continued)

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■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have ■ high blood pressure ■ liver disease ■ diabetes ■ thyroid disease ■ heart disease ■ glaucoma (Nighttime only) ■ cough that occurs with too much phlegm (mucus) ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ 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

Drug Facts (continued)

■ taking sedatives or tranquilizers (Nighttime only)
When using this product
■ do not exceed recommended dosage
■ excitability may occur, especially in children (Nighttime only)
■ marked 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 ■ new symptoms occur
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present
■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
Do not take DAYTIME and NIGHTTIME products at the same time.

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Other information

■ each caplet contains: sodium 3 mg
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■ see end flap for expiration date and lot number

Drug Facts (continued)

Inactive ingredients (Daytime only)
corn starch, croscopolone, DSC yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Inactive ingredients (Nighttime only)
corn starch, croscopolone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, 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

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REV0922A503A47308
B-1702503A4730083

Rite Aid 44-503A473C

COLD AND FLU SEVERE, DAYTIME, NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-5034
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5034-8	1 in 1 CARTON; Type 0: Not a Combination Product	06/30/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2

COLD AND FLU SEVERE DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin phenylephrine hcl tablet, film coated

Product Information

Item Code (Source)	NDC:11822-5347
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Route of Administration	ORAL
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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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	

D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
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: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor	MENTHOL	Imprint Code	44;503
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5347-9	8 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	06/30/2021	

Part 2 of 2

COLD AND FLU SEVERE NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet, film coated

Product Information

Item Code (Source)	NDC:11822-4753
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
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
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
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: 4ELV7Z65AP)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	17mm	
Flavor	MENTHOL	Imprint Code	44;473	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4753-9	8 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		06/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/30/2021	

Labeler - Rite Aid Corporation (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(11822-5034) , pack(11822-5034)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(11822-5034)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(11822-5034)

Revised: 5/2023

Rite Aid Corporation