

**COLD AND FLU DAYTIME NIGHTTIME SEVERE- acetaminophen,
dextromethorphan hbr, guaifenesin, phenylephrine hcl, triprolidine hcl
Walgreen Company**

Walgreens 44-042078

Active ingredients (in each 20 mL) (Daytime Cold & Flu)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Active ingredients (in each 20 mL) (Nighttime Severe Cold & Flu)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Phenylephrine HCl 10 mg
Triprolidine HCl 2.5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant
Antihistamine

Uses

- temporarily relieves these common cold and flu symptoms:
 - sore throat
 - nasal congestion
 - stuffy nose
 - minor aches and pains
 - sneezing (***Nighttime only***)
 - headache
 - cough
 - runny nose (***Nighttime only***)
 - itching of the nose or throat (***Nighttime only***)

- itchy, watery eyes due to hay fever (**Nighttime only**)
- sinus congestion and pressure
- temporarily reduces fever
- controls cough to help you get to sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (**Daytime only**)

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

- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma (**Nighttime only**)
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- 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**)

- high blood pressure

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**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nighttime only**)
- avoid alcoholic beverages (**Nighttime only**)
- use caution when driving a motor vehicle or operating machinery (**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 (Daytime only)

- **do not take more than directed**
- do not take more than 6 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

Directions (Nighttime only)

- **do not take more than directed**
- do not take more than 4 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided

- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

Other information

- **each 20 mL contains:** sodium 10 mg (**Daytime only**)
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients (Daytime only)

anhydrous citric acid, disodium edetate, FD&C blue #1, FD&C red #40, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose, xanthan gum

Inactive ingredients (Nighttime only)

anhydrous citric acid, FD&C blue #1, FD&C red #40, FD&C yellow #6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions?

Call 1-800-910-6874

Principal display panel

DAY & NIGHT PACK
NDC 0363-4278-45

<p><i>Walgreens</i> • WALGREENS • PHARMACIST RECOMMENDED† Compare to the active ingredients in Maximum Strength Mucinex® FAST-MAX® Cold & Flu & NIGHTSHIFT® Severe Cold & Flu††</p> <p>DAYTIME Cold & Flu</p> <p>ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT GUAIFENESIN / EXPECTORANT PHENYLEPHRINE HCl / NASAL DECONGESTANT</p>	<p>NIGHTTIME Severe Cold & Flu ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT PHENYLEPHRINE HCl / NASAL DECONGESTANT TRIPROLIDINE HCl / ANTIHISTAMINE Maximum Strength</p> <ul style="list-style-type: none"> • Relieves headache, body pain, sore throat, fever, itchy throat
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Maximum Strength

- Relieves headache, body pain, sore throat, fever, chest congestion, cough, nasal congestion, sinus congestion & pressure
- 12 years & older

SORE THROAT, FEVER, RICHY THROAT, COUGH, nasal congestion, runny nose & sneezing

- 12 years & older

2 - 6 FL OZ (177 mL) BOTTLES / TOTAL 12 FL OZ (355 mL)
 TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
 Do not take Daytime Cold & Flu and Nighttime Severe Cold & Flu at the same time.

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

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 DEERFIELD, IL 60015
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†Our pharmacists recommend the Walgreens brand.

We invite you to compare to national brands.

††This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademarks Maximum Strength Mucinex® FAST-MAX® Cold & Flu and NIGHTSHIFT® Severe Cold & Flu.

DAY & NIGHT PACK NDC 0363-4276-45

Walgreens 100% SATISFACTION GUARANTEED

DAYTIME Cold & Flu
 ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
 DEXTROMETHORPHAN HBR / COUGH SUPPRESSANT
 GUAIFENESIN / EXPECTORANT
 PHENYLEPHRINE HCl / NASAL DECONGESTANT

NIGHTTIME Severe Cold & Flu
 ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
 DEXTROMETHORPHAN HBR / COUGH SUPPRESSANT
 PHENYLEPHRINE HCl / NASAL DECONGESTANT
 TRIPROLIDINE HCl / ANTIHISTAMINE

Maximum Strength
 • Relieves headache, body pain, sore throat, fever, chest congestion, cough, nasal congestion, sinus congestion & pressure
 • 12 years & older

Maximum Strength
 • Relieves headache, body pain, sore throat, fever, itchy throat, cough, nasal congestion, runny nose & sneezing
 • 12 years & older

2 - 6 FL OZ (177 mL) BOTTLES / TOTAL 12 FL OZ (355 mL)

Drug Facts
Warnings
Directions
Other information
Questions or comments?

Walgreens 44-042078

COLD AND FLU DAYTIME NIGHTTIME SEVERE

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, triprolidine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4278
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4278-45	1 in 1 PACKAGE; Type 0: Not a Combination Product	10/21/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	177 mL
Part 2	1 BOTTLE, PLASTIC	177 mL

Part 1 of 2

COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

Item Code (Source)	NDC:0363-9042
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	BERRY (MIXED)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9042-45	177 mL in 1 BOTTLE, PLASTIC; 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	10/21/2023	

Part 2 of 2

COLD AND FLU SEVERE
acetaminophen, dextromethorphan hbr, phenylephrine hcl, triprolidine hcl solution

Product Information

Item Code (Source)	NDC:0363-8078
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	FRUIT (MIXED)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-8078-45	177 mL in 1 BOTTLE, PLASTIC; 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	10/21/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/21/2023	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.

967626305

manufacture(0363-4278) , pack(0363-4278)

Revised: 10/2023

Walgreen Company