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

Walgreens 44-078

Active ingredients (in each 20 mL)

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:

- nasal congestion
- sore throat
- minor aches and pains
- cough
- sinus congestion and pressure
- sneezing
- itching of the nose or throat
- runny nose
- itchy, watery eyes due to hay fever
- headache

- temporarily reduces fever
- controls cough to help you get to sleep

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

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

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

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.

Directions

- **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

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

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 or comments?

1-800-426-9391

Principal display panel

NDC 0363-8078-45

Walgreens
• WALGREENS •
PHARMACIST RECOMMENDED†
Compare to the active ingredients in
Maximum Strength Mucinex®
NIGHTSHIFT® Severe Cold & Flu††

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, itchy throat, cough, nasal congestion, runny nose & sneezing
- 12 years & older

6 FL OZ (177 mL)

†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 trademark Maximum Strength Mucinex® NIGHTSHIFT® Severe Cold & Flu.
DISTRIBUTED BY: WALGREEN CO., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Walgreens 44-078

COLD AND FLU SEVERE

acetaminophen, dextromethorphan hbr, phenylephrine hcl, triprolidine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**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:1WS297W6MV)	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	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
LNK International, Inc.		967626305	manufacture(0363-8078) , pack(0363-8078)

Revised: 10/2023

Walgreen Company