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

Walgreens 44-042

Active ingredients (in each 20 mL)

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

Purpose

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - nasal congestion
 - stuffy nose
 - minor aches and pains
 - headache
 - cough
 - sore throat
 - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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
- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

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

- blisters
- rash
- skin reddening

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)
- liver disease
- thyroid disease
- heart disease
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- nervousness, dizziness, or sleeplessness 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 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

Other information

- each 20 mL contains: sodium 10 mg
- 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, 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

Questions or comments?

1-800-426-9391

Principal Display Panel

Walgreens

• WALGREENS •
PHARMACIST RECOMMENDED†
Compare to the active ingredients
in Maximum Strength Mucinex®
FAST-MAX® Cold & Flut†

DAYTIME Cold & Flu

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT
GUAIFENESIN / EXPECTORANT
PHENYLEPHRINE HCI / NASAL DECONGESTANT

Maximum Strength

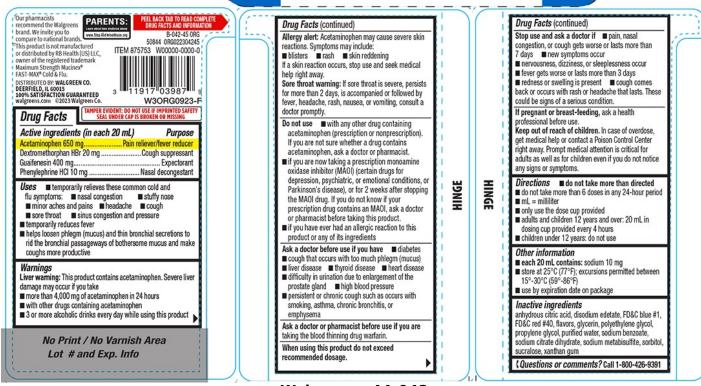
 Relieves headache, body pain, sore throat, fever, chest congestion, cough, nasal congestion, sinus congestion & pressure • 12 years & older

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 ®
FAST-MAX® Cold & Flu.
DISTRIBUTED BY: WALGREEN CO.
DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING





Walgreens 44-042

COLD AND FLU

acetaminophen, dextromethorphan hbr, quaifenesin, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9042
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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)	GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWIA)				
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	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(0363-9042) , pack(0363-9042)	

Revised: 10/2023 Walgreen Company