COLD, FLU, AND SORE THROAT- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
Walgreen Company

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.

Walgreens 44-616-CFS

Active ingredients (in each caplet)

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

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - nasal congestion
  - sore throat
  - headache
  - minor aches and pains
  - cough
- 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 in 24 hours, which is the maximum daily amount
- 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

- liver disease
- diabetes
- heart disease
- difficulty in urination due to enlargement of the prostate gland
- thyroid disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- 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

- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- 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 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.

Directions

- **do not take more than directed**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets 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)

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- use by expiration date on package

Inactive ingredients

corn starch, crospovidone, FD&C blue #1 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

Walgreens

NDC 0363-6160-09

Compare to Maximum Strength
Mucinex® Fast-Max® Cold, Flu &
Sore Throat active ingredients††

Cold, Flu &
Sore Throat

ACETAMINOPHEN 325 mg /
PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT
GUAIFENESIN 200 mg / EXPECTORANT
PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

MAXIMUM STRENGTH

MULTI-SYMPTOM

• Relieves headache, fever, sore throat, chest congestion & stuffy nose

• Control cough •Thins & loosens mucus

•12 years & older

20 CAPLETS

ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

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200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
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Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey
††This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Maximum Strength

Mucinex® Fast-Max® Cold, Flu & Sore Throat.
50844 ORG011761609 ORG0917-F

Walgreens 44-616

COLD, FLU, AND SORE THROAT

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-6160
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
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)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;616
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-6160-09	2 in 1 PACKAGE	04/07/2013	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-6160-01	3 in 1 PACKAGE	04/07/2013	02/07/2021
2		10 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	04/07/2013	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-6160)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-6160)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-6160)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-6160)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-6160)

Revised: 4/2020

Walgreen Company