

COLD FLU AND SORE THROAT- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

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.

Walgreen Co. Cold, Flu & Sore Throat Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- temporarily promotes nasal and/or sinus drainage
- 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
- 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if

you are taking the blood thinning drug warfarin

When using

this product do not use more than directed

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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick 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 (see Overdose warning)
- do not take more than 5 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- each 20 mL contains: sodium 7 mg
- store at 20-25°C (68-77°F)
- dosing cup provided
- do not refrigerate

Inactive ingredients

anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triethyl citrate, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

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

MUCUS RELIEF

Cold, Flu & Sore Throat

ACETAMINOPHEN /

PAIN RELIEVER & FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

GUAIFENESIN / EXPECTORANT

PHENYLEPHRINE HCl / NASAL DECONGESTANT

MAXIMUM STRENGTH

Relieves headache, fever, sore throat, nasal & chest congestion

Thins & loosens mucus

Controls cough

12 years & older

6 FL OZ (180 mL)

Walgreens

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

MUCUS RELIEF

NDC 0363-1209-30

Cold, Flu & Sore Throat

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: 16930 94 F1

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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Walgreens Pharmacist Survey
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ORG0118-F

ITEM 623979 W10107-031 8-F



Drug Facts

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|------------------------------------|-----------------------------|
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| Dextromethorphan HBr 20 mg | Cough suppressant |
| Guaifenesin 400 mg | Expectorant |
| Phenylephrine HCl 10 mg | Nasal decongestant |

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

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PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

: 16930 94 B1

Drug Facts (continued)

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Questions or comments?
1-800-719-9260

†† This product is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Fast-Max® Cold, Flu & Sore Throat.

Drug Facts (continued)

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COLD FLU AND SORE THROAT

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-1209 |
| 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) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|----------|------|--------------|--|
| Color | BLUE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0363-1209-30 | 1 in 1 CARTON | 08/04/2018 | |
| 1 | | 180 mL in 1 BOTTLE; 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 | 08/04/2018 | |

Labeler - Walgreen Company (008965063)

Revised: 5/2019

Walgreen Company