ADULT COLD, FLU AND SORE THROAT - acteaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Mckesson

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.

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adult cold, flu and sore throat multi-symptom

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
- sinus congestion and pressure
- cough due to minor throat and minor bronchial irritation
- 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 drain bronchial tubes and make coughs more productive

Warnings

Liver warning: This product contains acetaminophen. severe liver damage may occur if you take:

- more than 6 doses in 24 hours, which is maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product
- Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

Do not use

- **with any other drug containing acetaminophen** (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for children under 12 years of age
- 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.

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 persistent headache. 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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a poison control center right away. 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 6 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 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 20 mg

- store between 15-30ºC(59-86ºF)
- do not refrigerate
- dosing cup provided

Inactive ingredients

citric acid anhydrous, edetate disodium, FD and C blue 1, FD and C red 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

PDP

adult cold, flu and sore throat

multi-symptom

Calms headaches and fevers

Relives nasal and chest congestion,

Soothes cough,

Thins and loosens mucus

ACETAMINOPHEN

pain reliever/Fever reducer

DEXTROMETHORPHAN HBr

Cough Suppressant

GUAIFENESIN

Expectorant

PHENYLEPHRINE HCl

Nasal Decongestant

For Ages 12 and Over

MAXIMUM STRENGTH

6 FL OZ (177 mL)

Drug Facts

Active ingredients (in each 20 mL) Purpose

Acetaminophen 650 mg.....Pain reliever/fever reducer
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: ■ nasal congestion ■ sinus congestion and pressure ■ cough due to minor throat and bronchial irritation ■ 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 drain bronchial tubes and make coughs more productive

PEEL HERE FOR CONTINUED DRUG FACTS

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

*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Mucinex® Fast Max™ Cold, Flu and Sore Throat.

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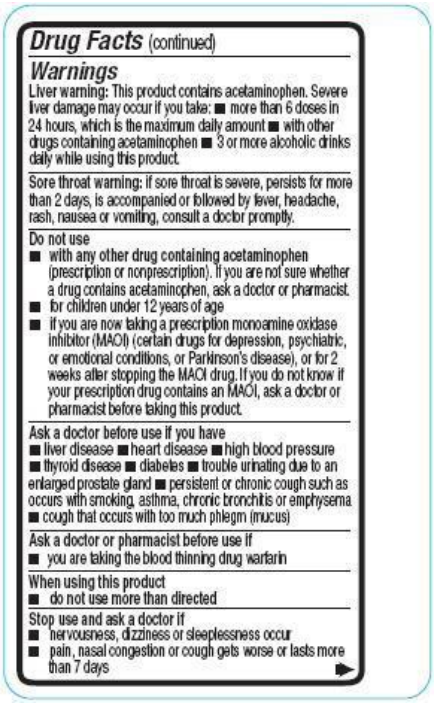


Drug Facts (continued)

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 6 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks daily while using this product.

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.

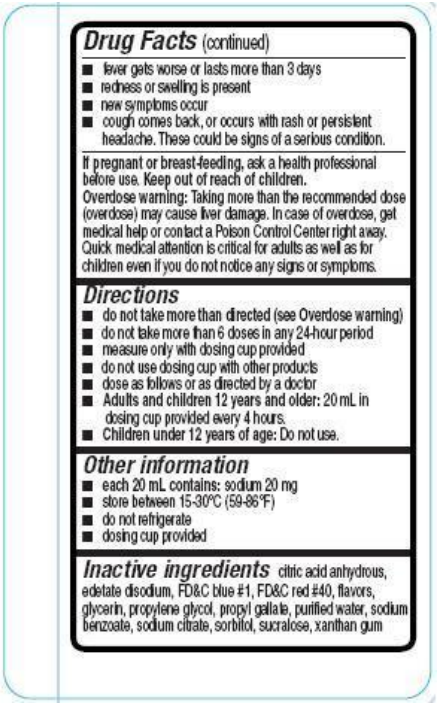
Do not use
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ for children under 12 years of age
■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs 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.

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



Drug Facts (continued)

■ 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 persistent headache. 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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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 6 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 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 20 mg
■ store between 15-30°C (59-86°F)
■ do not refrigerate
■ dosing cup provided

Inactive ingredients citric acid anhydrous, edetate disodium, FD&C blue #1, FD&C red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

ADULT COLD, FLU AND SORE THROAT

acteaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-080

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-080-36	177 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/01/2012	

Labeler - Mckesson (177667227)

Revised: 6/2013 Mckesson