CVS MAXIMUM STRENGTH COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin ,phenylephrine hcl liquid
CVS PHARMACY, INC

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.

CVS Maximum Strength Cold & Flu Relief

Drug Facts

Active ingredients (in each 20 mL)	***Purposes***
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:
    - cough
    - nasal congestion
    - minor aches and pains
    - sore throat
    - sinus congestion and pressure
    - 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 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

Generic Section

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.
- 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 (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you don’t 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 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 8 mg
- store at room temperature
- do not refrigerate

Inactive ingredients

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

Questions or comments?

1-866-467-2748

Principal Display Panel

Compare to the active ingredients in Maximum Strength Mucinex® Fast-Max® Cold, Flu

NDC 69842-566-06

Maximum Strength‡

Cold , Flu &

Sore Throat

Acetaminophen - Pain Reliever/Fever Reducer
Dextromethorphan HBr - Cough Suppressant
Guaifenesin - Expectorant
Phenylephrine HCl - Nasal Decongestant

- Controls Cough, Thins & Loosens Mucus
- Nasal & Chest Congestion
- Sinus Pressure & Congestion
- Body Pain, Headache, Fever & Sore Throat

For Ages 12+

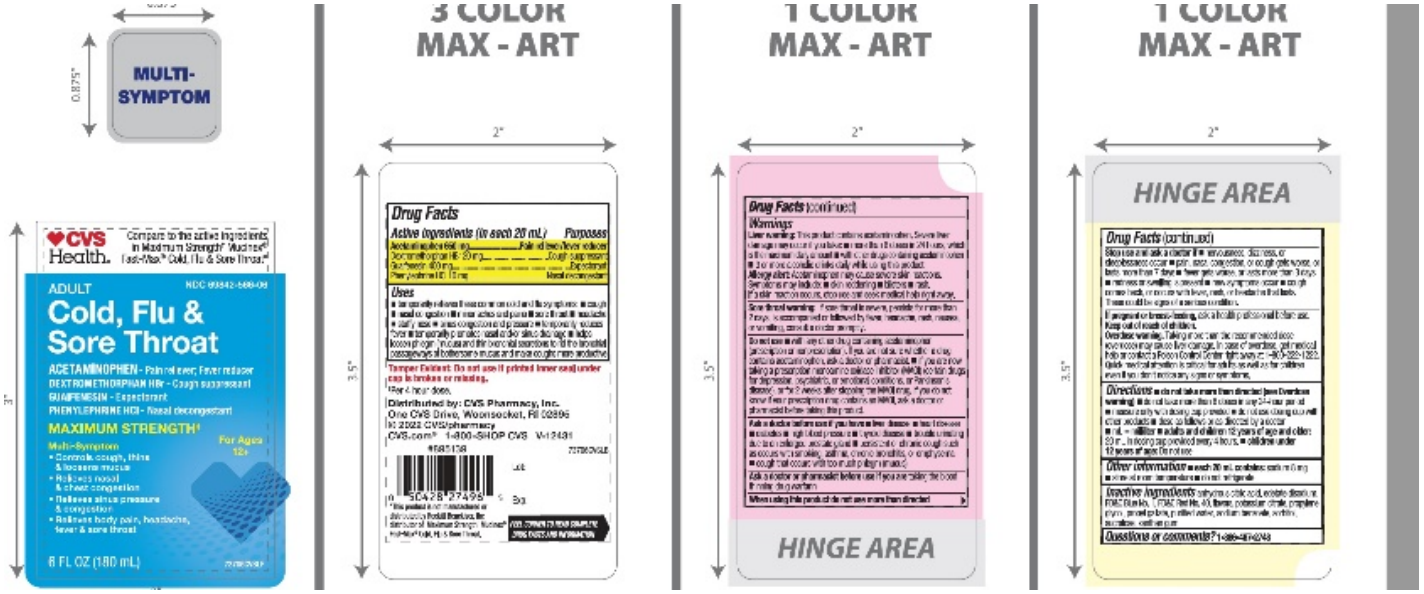
6 FL OZ (180 mL)

Do not use if printed seal under cap is broken or missing.

‡ Per 4-hour dose.

Distributed by:

*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Maximum Strength‡ Mucinex® Fast-Max® Cold, Flu & Sore Throat



CVS MAXIMUM STRENGTH COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin ,phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-566
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-566-06	180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/11/2022	

Labeler - CVS PHARMACY, INC (062312574)

Revised: 9/2023 CVS PHARMACY, INC