

**WINCO MAXIMUM STRENGTH COLD FLU AND SORE THROAT- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution**  
**WINCO FOODS, LLC**

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**Winco Foods Fast Acting Mucus Relief Cold, Flu & Sore Throat Maximum Strength**

**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 pain
  - sore throat
  - headache
  - stuffy nose
  - sinus congestion and pressure
- 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 everyday 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.
- 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 fever, 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:** 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 at 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 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
- mL = milliliter
- **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 No. 1, FD&C Red No. 40, flavor, potassium citrate, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

**Questions or comments?**

1-800-824-1706

Monday-Friday 9am – 4pm MST

**Principal Display Panel**

Compare to the active ingredients in Maximum Strength MUCINEX<sup>®</sup> FAST-MAX<sup>®</sup> Cold, Flu & Sore Throat

**Winco<sup>®</sup> Foods**

Fast Acting Mucus Relief

COLD, FLU & SORE THROAT

Maximum Strength ‡

**Acetaminophen 650 mg/PAIN RELIEVER/FEVER REDUCER**

**DEXTROMETHORPHAN HBr 20 mg/ COUGH SUPPRESSANT**

**GUAIFENESIN 400 mg/ EXPECTORANT**

**PHENYLEPHRINE HCl 10 mg/ NASAL DECONGESTANT**

Adult Formula, For Ages 12 & Over

4 Hour Dosing

6 FL OZ (180 mL)

\*This product is not manufactured or distributed by RECKITT BENCKISER, the distributor of Maximum Strength <sup>†</sup>MUCINEX® FAST-MAX® Cold, Flu & Sore throat.

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

**<sup>†</sup>Per 4-hour dose.**

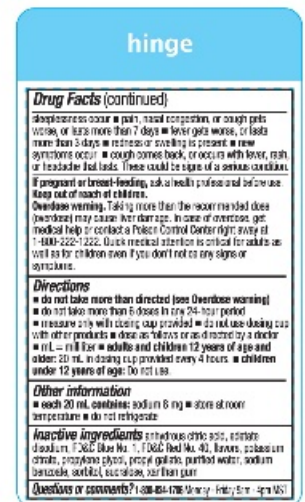
**DISTRIBUTED BY:**

**WINCO FOODS, LLC,**

**BOISE, ID 83704**

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PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION



## WINCO MAXIMUM STRENGTH COLD FLU AND SORE THROAT

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67091-457
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-457-06	180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/16/2019	

Labeler - WINCO FOODS, LLC (056098817)