

WINCO FOODS MULTI-SYMPTOM SEVERE COLD GREEN TEA AND HONEY LEMON FLAVORS- acetaminophen, dextromethorphan hbr and phenylephrine hcl granule, for solution Winco Foods, LLC

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.

Winco Foods Multi-Symptom Severe Cold with Green Tea and Honey Lemon flavors

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Active ingredients (in each packet) Purpose

Acetaminophen 500 mgPain reliever/Fever reducer
Dextromethorphan hydrobromide 20 mgCough suppressant
Phenylephrine hydrochloride 10 mg.....Nasal decongestant.

Uses

- Temporarily relieves these symptoms due to a cold:
- minor aches and pains - headache - minor sore throat pain
- nasal and sinus congestion - cough due to minor throat and bronchial irritation
- Temporarily reduces fever.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take - more than 6 packets in 24 hours, which is the maximum daily amount - 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: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly.

Do not use

- In a child under 4 years of age.
- If you are allergic to acetaminophen.
- with any other drug containing acetaminophen (prescription and nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 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 a 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 - cough that occurs with too much phlegm (mucus) - cough that lasts or is chronic such as occurs with smoking, asthma 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

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- symptoms do not get better or worsen
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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 care professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

- do not use more than directed
- take every 4 hours; not to exceed 6 packets in 24 hours or as directed by a doctor.

Age	Dose
children under 4 years of age	do not use
children 4 to under 12 years of age	do not use unless directed by a doctor
adults and children 12 years of age and over	one packet

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.

- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other information

- each packet contains: potassium 8 mg, sodium 15 mg, calcium 120 mg.
- phenylketonurics: contains phenylalanine 13 mg per packet

- store at controlled room temperature 20-25C (68-77F). Protect from heat and moisture.

Acesulfame potassium, anhydrous citric acid, Aspartame, calcium phosphate dibasic, caramel, D and C yellow No. 10, flavors, Maltodextrin, silicon dioxide, Sodium Citrate, Starch, Sucrose.



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acetaminophen, dextromethorphan hbr and phenylephrine hcl granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-291
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	yellow (Caramel color) , yellow (D and C Yellow No. 10)	Score	
Shape		Size	
Flavor	HONEY (Natural Honey and Lemon flavor) , LEMON (Natural Honey and Lemon Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-291-06	6 in 1 BOX; Type 0: Not a Combination Product	06/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/06/2016	

Labeler - Winco Foods, LLC (056098817)