

**TOPCARE COLD AND SORE THROAT LEMON FLAVOR- acetaminophen, pheniramine maleate, phenylephrine hcl granule, for solution**

**TOPCARE (Topco Associates 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.*

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**Topcare Cold and Sore Throat Lemon Flavor**

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Active Ingredients (in each packet)	Purpose
Acetaminophen 325 mg.....	Pain reliever/Fever reducer
Pheniramine maleate 20 mg.....	Antihistamine
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 congestion - temporarily reduces fever
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose - sneezing - itchy nose and throat - itchy, watery eyes.

**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.

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

**Do not use** - 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.

- with any other product containing acetaminophen (see Overdose Warning).

**Ask a doctor before use if you have**

- liver disease - heart disease - high blood pressure - thyroid disease - diabetes - glaucoma - a breathing problem such as emphysema, asthma, or chronic bronchitis - trouble urinating due to an enlarged prostate gland - a sodium-restricted diet.

**Ask a doctor or pharmacist before use if you are taking**

- sedatives or tranquilizers - the blood thinning drug warfarin.

**When using this product**

- do not exceed recommended dosage
- avoid alcoholic drinks - may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- pain or nasal congestion 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
- sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting. 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.

**Overdose Warning:** Taking more than the recommended dose can cause serious health problems, including serious liver damage. 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.

**Directions**

- do not use more than directed (see Overdose Warning)
- take every 4 hours; not to exceed 6 packets in 24 hours or as directed by a doctor
- adults and children 12 years of age and over: dissolve contents of one packet in 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- children under 12 years of age: consult a doctor
- 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: sodium 66 mg
- store at controlled room temperature 20-25C (68-77F).

Citric acid, D and C Yellow 10, Ethylcellulose, FD and C Red 40, Flavor, Microcrystalline cellulose, Povidone, Silicon Dioxide, Sodium Citrate, Starch, Sugar and Vitamin C.



## TOPCARE COLD AND SORE THROAT LEMON FLAVOR

acetaminophen, pheniramine maleate, phenylephrine hcl granule, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-802
<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	325 mg
<b>Pheniramine Maleate</b> (UNII: NYW905655B) (Pheniramine - UNII:134FM9ZZ6M)	Pheniramine Maleate	20 mg
<b>Phenylephrine hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine hydrochloride	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>Citric acid monohydrate</b> (UNII: 2968PHW8PP)	
<b>Ethylcellulose (100 MPAS)</b> (UNII: 47MLB0F1MV)	

<b>Cellulose, microcrystalline</b> (UNII: OP1R32D61U)	
<b>Povidone</b> (UNII: FZ989GH94E)	
<b>Silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Sodium citrate</b> (UNII: 1Q73Q2JULR)	
<b>Sucrose</b> (UNII: C151H8M554)	
<b>Ascorbic acid</b> (UNII: PQ6CK8PD0R)	

<b>Product Characteristics</b>			
<b>Color</b>	yellow (D and C Yellow 10) , red (FD and C Red 40)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	LEMON (Nature Lemon Flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-802-06	6 in 1 BOX		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/20/2014	

**Labeler** - TOPCARE (Topco Associates LLC) (006935977)