

**TOPCARE DAYTIME SEVERE COLD AND COUGH BERRY INFUSED WITH MENTHOL AND GREEN TEA FLAVORS- acetaminophen, dextromethorphan hbr and 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.*

**TopCare Daytime Severe Cold and Cough Berry infused with Menthol and Green Tea flavors**

Active ingredients (in each packet)	Purpose
Acetaminophen 650 mg .....	Pain reliever/Fever reducer
Dextromethorphan hydrobromide 20 mg .....	Cough suppressant
Phenylephrine hydrochloride 10 mg.....	Nasal decongestant.

**Uses**

- Temporarily relieves:
  - 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.

**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 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 - a breathing problem such as emphysema, asthma, or chronic bronchitis - 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.

#### Directions

- do not use more than directed
- 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 into 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: potassium 8 mg, sodium 20 mg
- phenylketonurics: contains phenylalanine 14 mg per packet
- store at controlled room temperature 20-25C (68-77F). Protect from excessive heat and moisture.

Acesulfame K, Aspartame, Citric Acid, FD and C Blue No. 1, FD and C Red No. 40, Maltodextrin, Menthol, Natural Flavors, Sodium Citrate, Starch and Sugar.



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acetaminophen, dextromethorphan hbr and phenylephrine hcl granule, for solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-540
<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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg

## Inactive Ingredients

Ingredient Name	Strength
Acesulfame (UNII: MA3UYZ6K1H)	
Aspartame (UNII: Z0H242BBR1)	
Citric acid monohydrate (UNII: 2968PHW8QP)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Sucrose (UNII: C151H8M554)	

## Product Characteristics

<b>Color</b>	red (FD and C red No. 40) , blue (FD and C blue No. 1)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY (Berry infused with menthol and green tea flavors) , MENTHOL (menthol)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-540-06	6 in 1 BOX		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/18/2014	

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

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