

TOPCARE DAY TIME SEVERE COLD AND COUGH BERRY INFUSED WITH MENTHOL AND GREEN TEA FLAVORS- acetaminophen, dextromethorphan hbr, and phenylephrine hcl. granule, for solution
Quality Home Products

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.

Day time 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
- 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.

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.

As 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.

TopCare

FOR DAYTIME RELIEF
Daytime Severe Cold & Cough
 ACETAMINOPHEN - Pain Reliever • Fever Reducer
 DEXTROMETHORPHAN HBR - Cough Suppressant
 PHENYLEPHRINE HCl - Nasal Decongestant
 NDC 64525-0543-6

FOR DAYTIME RELIEF
Daytime Severe Cold & Cough
 ACETAMINOPHEN
 Pain Reliever • Fever Reducer
 DEXTROMETHORPHAN HBR
 Cough Suppressant
 PHENYLEPHRINE HCl
 Nasal Decongestant

FOR RELIEF OF
 • Nasal and Sinus Congestion
 • Cough • Body Ache
 • Sore Throat Pain
 • Headache • Fever

Berry Infused with Menthol and Green Tea flavors

6 PACKETS

Topco.
 TOPCO ASSOCIATES LLC
 Creative Services
 7711 Gross Point Road
 Skokie, IL 60077
 ph 847.676.3030
 fax 847.676.9493

PACKER: Quality Home Products
 BRAND: TopCare
 ITEM DESCRIPTION & UPC NUMBER
 Daytime Severe Cold & Cough
 TOPCO PROJECT NUMBER:
 18786

DATE: 7/27/09

TOPCARE DAY TIME SEVERE COLD AND COUGH BERRY INFUSED WITH MENTHOL AND GREEN TEA FLAVORS

acetaminophen, dextromethorphan hbr, and phenylephrine hcl. granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64525-0553
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	650 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextrose - UNII:IY9XDZ35W2)	Dextromethorphan Hydrobromide	20 mg
Phenylephrine Hydrochloride (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

Color	red (FD & C red No. 40) , blue (FD & C blue No.1)	Score	
Shape		Size	
Flavor	BERRY (Berry infused with menthol & Green tea flavors) , MENTHOL (menthol)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64525-0553-6	6 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2009	

Labeler - Quality Home Products (205554157)

Revised: 10/2009

Quality Home Products