PREMIER VALUE NIGHT TIME SEVERE COLD AND COUGH HONEY LEMON INFUSED WITH CHAMOMILE AND WHITE TEA FLAVORS- acetaminophen, diphenhydramine hcl, and phenylephrine hcl. granule, for solution
Premier Value

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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night time severe cold and cough honey lemon infused with chamomile and white tea flavors

Active ingredients (in each packet) **Purpose**

Acetaminophen 650 mg .....Pain reliever/Fever reducer

Diphenhydramine hydrochloride 25 mg .....Antihistamine/Cough suppressant

Phenylephrine hydrochloride 10 mg .....Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:

- minor aches and pains - minor sore throat pain

- headache - nasal and sinus congestion

- runny nose - sneezing

- itchy nose and throat - itchy, watery eyes due to hay fever

- 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: 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

- In a child under 4 years of age

- If you are allergic to Acetaminophen

- with any other drug containing acetaminophen (prescription and non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- with any other product containing diphenhydramine, even one used on the skin

-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 - glaucoma

- 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.

- a sodium restricted diet.

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers.
- Taking the blood thinning drug warfarin

When using this product

- do not exceed recommended dosage

- avoid alcoholic drinks - marked drowsiness may occur

- 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

- 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.

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 7 mg, sodium 46 mg

- phenylketonurics: each packet contains phenylalanine 13 mg

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

Acesulfame potassium, anhydrous citric acid, aspartame, caramel, D and C Yello 10, maltodextrin, natural flavors, sodium citrate, starch and sugar.

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acetaminophen, diphenhydramine hcl, and phenylephrine hcl. granule, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-755
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 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	yellow (Carmel Color) , yellow (D & C Yellow 10)	**Score**	
Shape		**Size**	
Flavor	HONEY (Natural Honey & Lemon Flavor) , LEMON (Natural Honey & Lemon Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-755-06	6 in 1 BOX; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/24/2016	

Labeler - Premier Value (101668460)

Revised: 3/2016 Premier Value