

FAMILY DOLLAR NIGHTTIME SEVERE COLD AND COUGH HONEY LEMON INFUSED WITH CHAMOMILE AND WHITE TEA FLAVORS- acetaminophen, diphenhydramine hcl 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.

Family Wellness Nighttime Severe Cold and Cough Honey lemon infused with Chamomile and White tea flavors

Active ingredients (in each packet) Purpose

Acetaminophen 650 mgPain reliever/Fever reducer

Diphenhydramine hydrochloride 25 mgAntihistamine/Cough 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
- runny nose - sneezing - itchy, watery eyes due to hay fever
- itchy nose and throat
- 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 redness - 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 nonprescription). 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 (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 - glaucoma - 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.

- 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 10 mg, sodium 47 mg

- phenylketonurics: each packet contains phenylalanine 13 mg

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

Acesulfame potassium, anhydrous citric acid, Aspartame, Caramel Color, D and C Yellow 10, Maltodextrin, Natural Flavors, Sodium Citrate, Starch and Sugar.



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64525-0566
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDRO CHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDRO CHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
ACESULFAME (UNII: MA3UYZ6K1H)	
ASPARTAME (UNII: Z0H242BBR1)	

Product Characteristics

Color	yellow (Caramel Color) , yellow (D & C Yellow 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:64525-0566-6	6 in 1 BOX; Type 0: Not a Combination Product	11/24/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/24/2015	

Labeler - Quality Home Products (205554157)

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