

QUALITY CHOICE NIGHT TIME 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.

night time 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 mgNasal decongestant

Uses

- temporarily relieves
 - 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 - 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 non prescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 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 us 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.

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.
- 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 7 mg,
sodium 46 mg
- phenylketonurics: contains phenylalanine
13 mg per packet
- store at controlled room temperature
20-25C (68-77F). Protect from
excessive heat and moisture.

Drug Facts

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:
 • 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 • 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.
 • 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.

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When using this product
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 • 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.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health care professional before use. **Keep out of reach of children.**
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 • 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
 • phenylephrine: contains phenylalanine 13 mg per packet
 • store at controlled room temperature 20-25°C (68-77°F). Protect from excessive heat and moisture.

Inactive ingredients:
 Acesulfame K, aspartame, caramel color, citric acid, D&C Yellow 10, maltodextrin, natural flavors, sodium citrate, starch and sugar.

DO NOT USE IF SEALED PACKET IS TORN OR BROKEN.

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BUY   Made in Canada

NDC 64525-0542-6 ***Compare to Theraflu® Nighttime Severe Cold & Cough**

QC QUALITY CHOICE

NIGHTTIME SEVERE COLD & COUGH

ACETAMINOPHEN • PAIN RELIEVER-FEVER REDUCER
DIPHENHYDRAMINE HCl • ANTIHISTAMINE • COUGH SUPPRESSANT
PHENYLEPHRINE HCl • NASAL DECONGESTANT

Nasal Congestion • Cough
Runny Nose • Sneezing
Body Ache • Sore Throat Pain
Headache • Fever

Honey Lemon
 Infused with Chamomile and White Tea Flavors

6 PACKETS

See new warnings information.

*This product is not affiliated with Novartis Consumer Health, Inc., owner of the registered trademark, Theraflu®.

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ITEM No. 95978



COLOURS US

QUALITY CHOICE NIGHT TIME SEVERE COLD AND COUGH HONEY LEMON INFUSED WITH CHAMOMILE AND WHITE TEA FLAVORS

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64525-0550
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:64525-0550-6	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

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