

**WESTERN FAMILY 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.*

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**Western Family Nighttime 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:
- 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.

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 (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.

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.
- Acesulfame K, Aspartame, Caramel Color, Citric Acid, D and C Yellow 10, Maltodextrin, Natural Flavors, Sodium Citrate, Starch and Sugar.



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acetaminophen, diphenhydramine hcl and phenylephrine hcl granule, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64525-0564
<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>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 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>	yellow (Caramel Color) , yellow (D & C Yellow 10)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY (Natural Honey and Lemon Flavor) , LEMON (Natural Honey and Lemon Flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64525-0564-6	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	06/04/2015	

**Labeler** - Quality Home Products (205554157)

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