THERAFLU SEVERE COLD RELIEF NIGHTTIME- acetaminophen, diphenhydramine hydrochloride powder, for solution
JC World Bell Wholesale Co., Inc.

THERAFLU SEVERE COLD RELIEF NIGHTTIME, Honey (Honey Lemon Flavor)

Drug Facts

Active ingredients (in each packet)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Purposes

Pain reliever/Fever reducer

Antihistamine/Cough suppressant

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 or 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 4,000 mg of acetaminophen in 24 hours • 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 12 years of age • if you are allergic to acetaminophen • with any other drug containing acetaminophen (prescription or 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 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 an 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 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

• 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

• fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • cough comes back or occurs with rash or headache that lasts • pain, cough or nasal congestion gets worse or lasts more than 7 days These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health 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 directedtake every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

• 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 23 mg • **phenylketonurics:** contains phenylalanine 13 mg per packet • store at controlled room temperature 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, f lavors, maltodextrin, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

Questions or comments?

1-855-328-5259

Package Labeling:

1-855-328-5259

*Temporarily controls cough to help you rest. This is not a sleep aid.

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

Acetaminophen 650 mg ..... Pain reliever/Fever reducer
Diphenhydramine HCl 25 mg ..... Antihistamine/Cough suppressant
Phenylephrine HCl 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 or 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 4,000 mg of acetaminophen in 24 hours • 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 12 years of age • if you are allergic to acetaminophen • with any other drug containing acetaminophen (prescription or 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 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 an 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 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 • pain, cough or nasal congestion gets worse or lasts more than 7 days • cough comes back or occurs with rash or headache that lasts These could be signs of a serious condition. **If pregnant or breast-feeding,** ask a health 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, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

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children under 12 years of age	do not use

• 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 23 mg • **phenylketonurics:** contains phenylalanine 13 mg per packet • store at controlled room temperature 20-25°C (68-77°F). Protect product from heat and moisture. ***Inactive ingredients*** acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

Questions or comments? **1-855-328-5259**

Distributed by: Haleon, Warren, NJ 07059
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THERAFLU SEVERE COLD RELIEF NIGHTTIME

acetaminophen, diphenhydramine hydrochloride powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50269-101(NDC:0067-0101)
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

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	white (white to off-white, yellow and beige)	**Score**	
Shape		**Size**	
Flavor	HONEY (Lemon)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-101-06	20 in 1 BOX	12/01/2023	
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2023	

Labeler - JC World Bell Wholesale Co., Inc. (805257581)

Establishment

Name	Address	ID/FEI	Business Operations
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-101)