QUALITY CHOICE SEVERE COLD AND COUGH NIGHTTIME- acetaminophen, diphenhydramine, phenylephrine powder, for solution
Chain Drug Manufacturing Assn

QC Quality Choice Severe Cold and Cough Nighttime 6 Packets

Active ingredients (in each packet)

Acetaminophen, 650 mg

Diphenhydramine hydrochloride 25 mg

Phenylephrine hydrochloride 10 mg

Purposes

Pain reliever / fever reducer

Antihistamine / Cough Suppressant

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 a 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

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. There 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 at 1-800-222-1222. 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, not to exceed 5 packets in 24 hours unless directed by a doctor

Age	Dose
children 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 6 mg**
- store at room temperature. Protect from excessive heat and moisture.

Inactive ingredients

citric acid, FD& C yellow#6, flavors, maltodextrin, potassium chloride, silica, sucralose, sucrose,

Questions or comments?

1-866-467-2748

Additional Information Listed On Other Panels

QC Quality Choice

***Compare to the Active Ingredients in Theraflu® Nighttime Severe Cold &Cough**

Severe Cold & Cough

Nighttime

Acetaminophen - Pain Reliever/ Fever Reducer

Diphenhydramine HCl - Antihistamine/ Cough Suppressant

Phenylephrine HCl - Nasal Decongestant

Aspartame Free● Sodium Free

Relieves **:**
Nasal Congestion | Cough | Runny Nose | Sneezing | Body Ache | Sore Throat Pain | Headache | Fever.

Honey Lemon Infused with Chamomile and White Tea Flavors

6 Packets

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE, KEEP CARTON FOR REFERENCE, DO NOT DISCARD,

TAMPER EVIDENT INNER UNIT: DO NOT USE IF SEALED PACKET IS TORN OR BROKEN.

Distributed by: C.D.M.A., Inc ©

43157 W. 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Questions: 248-449-9300

*This product is not manufactured or distributed by GSK Consumer Healthcare, owner of the registered trademark Theraflu® Nighttime Severe Cold & Cough.

Principal Display

QUALITY CHOICE SEVERE COLD AND COUGH NIGHTTIME

acetaminophen, diphenhydramine, phenylephrine powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-291
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-291-06	6 in 1 CARTON	07/16/2018	
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	07/16/2018	

Labeler - Chain Drug Manufacturing Assn (011920774)

Revised: 11/2023 Chain Drug Manufacturing Assn