THERAFLU RELIEF MAX STRENGTH NIGHTTIME- acetaminophen, chlorpheniramine maleate and dextromethophan hbr powder, for solution
CVS PHARMACY

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.

Theraflu Nighttime Flu Relief Max Strength Drug Facts

Drug Facts

Active ingredients (in each packet)

Acetaminophen 1000 mg

Chlorpheniramine maleate 4 mg

Dextromethorphan HBr 30 mg

Purposes

Pain reliever/Fever reducer

Antihistamine

Cough suppressant

Uses

- temporarily relieves these symptoms due to a common cold:
  - headache
  - minor aches and pains
  - cough due to minor throat and bronchial irritation
  - minor sore throat pain
  - runny nose
- 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.
- 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 MAO, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- 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 the blood thinning drug warfarin
- taking sedatives or tranquilizers

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

- pain or cough gets worse or lasts more than 7 days

- 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. 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 6 hours, while symptoms persist. Do not take more than 3 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 6 mg
- store at room temperature. Protect from excessive heat and moisture.

Inactive ingredients

anhydrous citric acid, Caramel, flavor, maltodextrin, potassium chloride, silica, sucralose, sucrose

Questions or comments?

1-866-467-2748

Principal Display Panel

*Compare to the active ingredients in Theraflu Multi-Symptom Flu Relief Max Strength** Nighttime

NDC 51316-549-06

Nighttime

Flu Relief

MAX STRENGTH**

Acetaminophen Pain Reliever/Fever Reducer

Chlorpheniramine Maleate Antihistamine

Dextromethorphan HBr Cough Suppressant

Honey Lemon

Natural & Artificial Flavored

1 SINGLE DOSE

TO OPEN: CUT ALONG DOTTED LINE WITH SCISSORS DO NOT USE IF SEALED PACKET IS TORN OR BROKEN

*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Theraflu Multi-Symptom Flu Relief Max Strength** Nighttime.

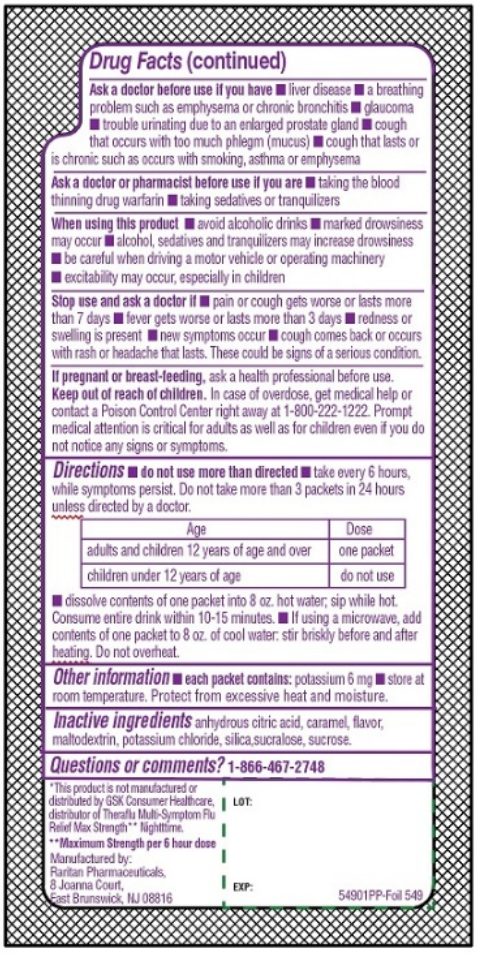
**Maximum Strength per 6 hours dose

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick, NJ 08816



THERAFLU RELIEF MAX STRENGTH NIGHTTIME

acetaminophen, chlorpheniramine maleate and dextromethophan hbr powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51316-549
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARAMEL (UNII: T9D99G2B1R)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-549-06	1 in 1 PACKET; Type 0: Not a Combination Product	04/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/17/2023	

Labeler - CVS PHARMACY (062312574)

Revised: 5/2023 CVS PHARMACY