NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, diphenhydramine, phenylephrine powder, for solution
FAMILY DOLLAR SERVICES INC

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.

Nighttime Severe Cold & Cough Honey lemon Infused with Chamomile & White Tea Flavors 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
- 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, 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 6 mg
- Aspartame free, sodium free
- 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

Compare to the active ingredients in THERAFLU Nighttime Severe Cold &Cold

NDC 55319-451-06

NIGHTTIME

SEVERE COLD & COUGH

Acetaminophen – Pain Reliever/Fever Reducer

Diphenhydramine HCl - Antihistamine/ Cough Suppressant

Phenylephrine HCl – Nasal Decongestant

Relieves

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

6 PACKETS

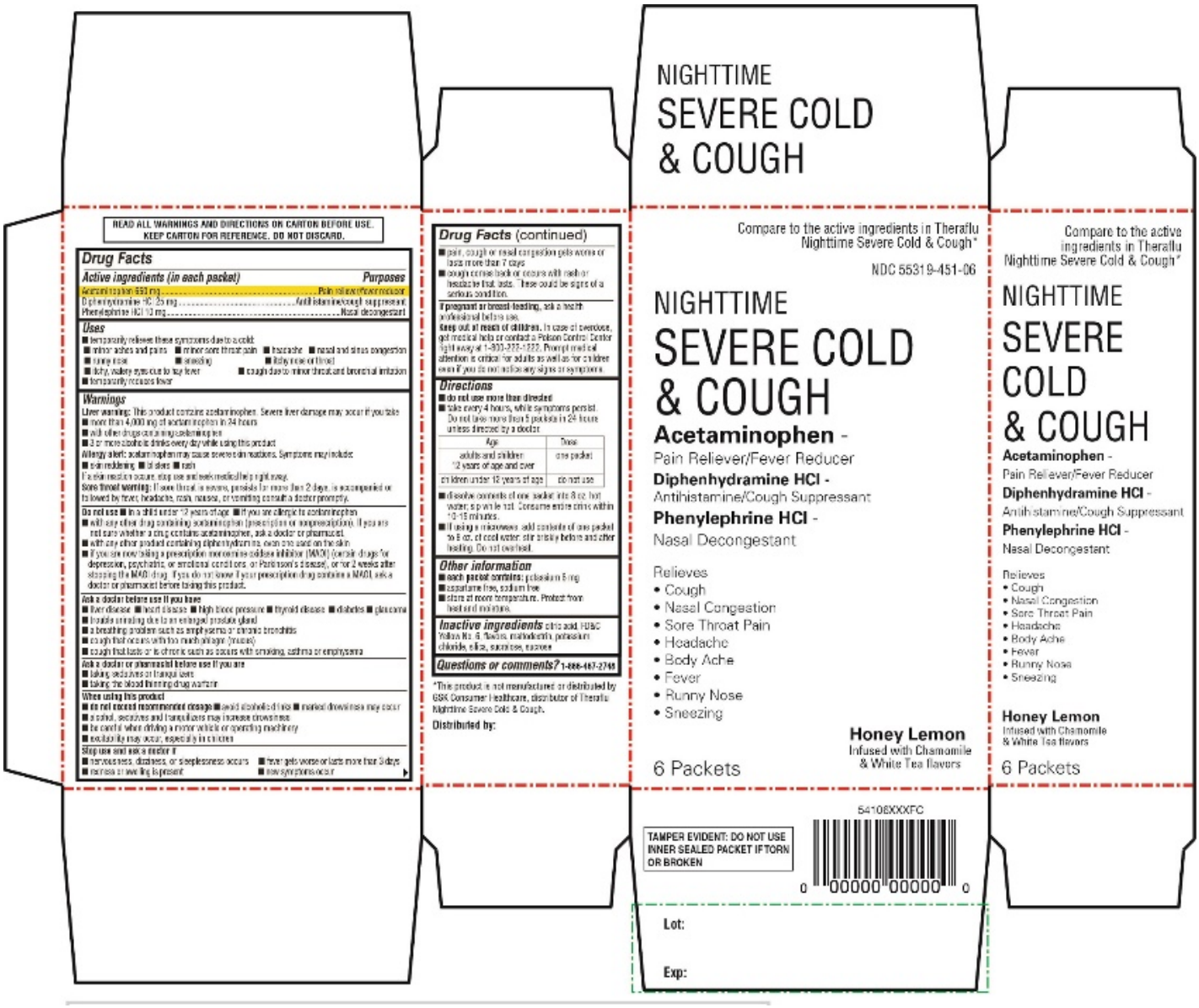
Honey Lemon

Infused with Chamomile and White Tea Flavors

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

*This product is not manufactured or distributed by GSK consumer Healthcare, distributor of TherafluNighttime Severe Cold & Cough.

Principal Display



NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine, phenylephrine powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55319-451
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:55319-451-06	6 in 1 CARTON	07/03/2023	
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 final	part341	07/03/2023	

Labeler - FAMILY DOLLAR SERVICES INC (024472631)

Revised: 7/2023 FAMILY DOLLAR SERVICES INC