THERAFLU SEVERE COLD RELIEF NIGHTTIME- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each packet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 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 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 last 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 6 packets in 24 hours unless directed by a doctor

1. Age	1. Dose
1. adults and children 12 years of age and over	1. one packet
1. children under 12 years of age	1. do not use

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consumer 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, FD&C yellow no. 6, flavors, maltodextrin, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

Questions or Comments?

call **1-800-328-5259**

Generic Section

TAMPER EVIDENT INNER UNIT

DO NOT USE IF SEALED THERAFLU PACKET IS TORN OR BROKEN

1-855-328-5259

Distributed by: **GSK Consumer Healthcare**
Warren, NJ 07059

62000000075407

HOT LIQUID THERAPY
that relieves:

Nasal and sinus congestion Cough

Sore throat pain Headache

Runny nose Fever

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.com

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

CARTON
RECYCLE

Principal Display Panel

NDC 0067-6801-02

MULTI-SYMPTOM **COLD RELIEF**

THERAFLU

SEVERE

COLD RELIEF

NIGHTTIME

ACETAMINOPHEN
PAIN RELIEVER/FEVER REDUCER

DIPHENHYDRAMINE HCl
ANTIHISTAMINE/COUGH SUPPRESSANT

PHENYLEPHRINE HCl
NASAL DECONGESTANT

HELPS YOU REST*

Hot liquid therapy
that relieves:

/Nasal and sinus congestion
/ Cough
/ Sore throat pain

/ Headache
/ Runny nose
/ Fever

Citrus & Green Tea

6 PACKETS

THERAFLU SEVERE COLD RELIEF NIGHTTIME

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-6801
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	white (white to off-white) , yellow (yellow, beige/brown granules)	**Score**	
Shape		**Size**	
Flavor	CITRUS (Green Tea & Citrus)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-6801-02	6 in 1 CARTON; Type 0: Not a Combination Product	01/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/20/2022	

Labeler - Haleon US Holdings LLC (079944263)