THERAFLU NIGHTTIME MULTI-SYMPTOM SEVERE COLD POWDER- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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.

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

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. 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, sucrose, tribasic calcium phosphate

Questions or Comments?

call **1-800-452-0051**

Principal Display Panel

NDC 0067-8124-06

***THERAFLU*®**

NIGHTTIME

MULTI-SYMPTOM

SEVERE COLD

ACETAMINOPHEN-PAIN RELIEVER/FEVER REDUCER

DIPHENHYDRAMINE HCl-ANTIHISTAMINE/COUGH SUPPRESSANT

PHENYLEPHRINE HCl-NASAL DECONGESTANT

- **NASAL CONGESTION**
- **SORE THROAT PAIN**
- **COUGH • HEADACHE**
- **BODY ACHE • FEVER**
- **RUNNY NOSE**
- **SNEEZING**

6 PACKETS

Theraflu® provides powerful relief from your severe cold and flu symptoms.

www.theraflu.com

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

TAMPER EVIDENT INNER UNIT

DO YOU USE IF SEALED THERAFLU PACKET IS TORN OR BROKEN.

Distributed by: **Novartis Consumer Health, Inc.**

Parsippany, NJ 07054-0622

Made in Canada

12211

THERAFLU NIGHTTIME MULTI-SYMPTOM SEVERE COLD POWDER

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8124
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 (UNII: 1Q73Q2JULR)	
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		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0067-8124-06	6 in 1 CARTON; Type 0: Not a Combination Product	07/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/15/2015	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Inc.		205475333	MANUFACTURE(0067-8124) , ANALYSIS(0067-8124) , PACK(0067-8124) , LABEL(0067-8124)