

**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.*

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**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.**

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

Parsippany, NJ 07054-0622

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Made in Canada

12211

NDC 0067-8124-06

**NEW!**

# THERAFLU<sup>®</sup>

**NIGHTTIME**  
**MULTI-SYMPTOM**  
**SEVERE COLD**

ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER  
DIPHENHYDRAMINE HCl - ANTIHISTAMINE/COUGH SUPPRESSANT  
PHENYLEPHRINE HCl - NASAL DECONGESTANT



**Lipton**<sup>®</sup>

Green Tea  
& Citrus  
Flavors

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

**6 PACKETS**

**THERAFLU NIGHTTIME MULTI-SYMPTOM SEVERE COLD POWDER**

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-8124
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)	

## Product Characteristics

<b>Color</b>	WHITE (white to off-white) , YELLOW (yellow, beige/brown granules)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

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

## Marketing Information

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
GSK Consumer Health, Inc.		129836151	MANUFACTURE(0067-8124) , ANALYSIS(0067-8124) , PACK(0067-8124) , LABEL(0067-8124)

Revised: 6/2021

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC