

**THERAFLU MULTI-SYMPTOM SEVERE COLD- acetaminophen,  
dextromethorphan hbr, phenylephrine hcl powder, for solution  
Haleon US Holdings LLC**

-----  
***Drug Facts***

***Active ingredients (in each packet)***

Acetaminophen 500 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

***Purposes***

Pain reliever/fever reducer

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
  - 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.
- 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
- trouble urinating due to an enlarged prostate gland
- 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

### **When using this product**

- **do not exceed recommended dosage**

### **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 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. 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 10 mg, sodium 19 mg
- **phenylketonurics:** contains phenylalanine 20 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, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate

### ***Questions or comments?***

call **1-855-328-5259**

### **Additional Information**

**READ ALL WARNING AND DIRECTIONS ON CARTON BEFORE USE.**

**KEEP CARTON FOR REFERENCE. DO NOT DISCARD.**

#### **PARENTS:**

Learn about teen medicine abuse

**[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)**

**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

©2019 GSK group of companies or its licensor.

Trademarks are owned by or licensed to the GSK group of companies.

**MULTI-SYMPTOM SEVERE COLD**

***COUGH***

***NASAL CONGESTION***

***SORE THROAT PAIN***

***HEADACHE***

***BODY ACHES***

***FEVER***

**Principal Display**

**NDC 0067-6426-06**

***THERAFLU***

**MULTI-SYMPTOM SEVERE COLD**

**Acetaminophen**

**Pain Reliever/Fever Reducer**

**Dextromethorphan HBr**

**Cough Suppressant**

**Phenylephrine HCl**

**Nasal Decongestant**

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***

**6 PACKETS**

**TEA INFUSIONS**

**GREEN TEA & HONEY LEMON FLAVORS**

62000000033901



## THERAFLU MULTI-SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-6426
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 237 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	20 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 237 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<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>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY (GREEN TEA & HONEY LEMON FLAVORS)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-6426-06	6 in 1 CARTON	07/01/2014	
1	NDC:0067-6426-01	237 mL 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 Drug	M012	07/01/2014	

**Labeler** - Haleon US Holdings LLC (079944263)