

**THERAFLU FLU RELIEF MAX STRENGTH DAYTIME NIGHTTIME COMBO PACK-  
acetaminophen, dextromethorphan hbr, and acetaminophen,  
chlorpheniramine maleate, dextromethorphan hbr  
Haleon US Holdings LLC**

-----

***Drug Facts***

**Theraflu Flu Relief Max Strength\* Daytime Powder**

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

Acetaminophen 1000 mg

Dextromethorphan HBr 30 mg

***Purposes***

Pain reliever/Fever reducer

Cough suppressant

***Uses***

- temporarily relieves these symptoms due to a common cold:
  - headache
  - minor aches and pains
  - cough due to minor throat and bronchial irritation
  - minor sore throat pain
- 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
- 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 the blood thinning drug warfarin

**When using this product**

- **do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 6 hours, while symptoms persist. Do not take more than 3 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. 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 20 mg
- phenylketonurics: contains phenylalanine 19.6 mg per packet
- store at a controlled room temperature at 20 - 25°C (68-77°F)

***Inactive ingredients***

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C

red no. 40, maltodextrin, natural and artificial flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

***Questions or comments?***

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

**Theraflu Flu Relief Max Strength Nighttime\* Powder**

***Drug Facts***

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

Acetaminophen 1000 mg

Chlorpheniramine maleate 4 mg

Dextromethorphan HBr 30 mg

***Purposes***

Pain reliever/Fever reducer

Antihistamine

Cough suppressant

## **Uses**

- temporarily relieves these symptoms due to a common cold:
  - headache
  - minor aches and pains
  - cough due to minor throat and bronchial irritation
  - minor sore throat pain
  - runny nose
- 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 a MAO, ask a doctor or pharmacist before taking this product.

## **Ask a doctor before use if you have**

- liver disease
- 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 the blood thinning drug warfarin

- taking sedatives or tranquilizers

**When using this product**

- ◦ 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**

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 6 hours, while symptoms persist. Do not take more than 3 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. 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 5 mg, sodium 22 mg
- phenylketonurics: contains phenylalanine 12.9 mg per packet

- store at a controlled room temperature at 20 - 25°C (68-77°F)

### ***Inactive ingredients***

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, maltodextrin, natural and artificial flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

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

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

### **Other Safety Information**

**READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE. KEEP CARTON FOR REFERENCE. DO NOT DISCARD.**

**DO NOT TAKE THE DAYTIME AND NIGHTTIME PRODUCTS AT THE SAME TIME.**

**DO NOT TAKE MORE THAN 3 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.**

**DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 4 HOURS AFTER THE LAST DOSE OF THE DAYTIME PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.**

**DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME OR TAKE MORE THAN 3 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.**

**PARENTS:** Learn about teen medicine abuse

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

\*Maximum Strength per 6 hour dose

**TAMPER-EVIDENT INNER UNIT. DO NOT USE IF NECKBAND PRINTED WITH "SEALED FOR SAFETY" IS TORN OR MISSING.**

1-855-328-5259

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

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

©2022 GSK group of companies or its licensor.

CM20324

### **Principal Display Panel**

**NDC 0067-7923-02**

***THERAFLU***

***FLU RELIEF***

**MAX STRENGTH\***

**USE ONLY AS DIRECTED**

**6 x DAYTIME**

**Acetaminophen** Pain Reliever/Fever Reducer

**Dextromethorphan HBr** Cough Suppressant

**6 x NIGHTTIME**

**Acetaminophen** Pain Reliever/Fever Reducer

**Chlorpheniramine Maleate** Antihistamine

**Dextromethorphan HBr** Cough Suppressant

**Hot liquid therapy that relieves:**

/ Fever

/ Body ache

/ Headache

/ Sore throat pain

/ Cough

/ Runny nose (Nighttime only)

**6 DAYTIME PACKETS**

**6 NIGHTTIME PACKETS**

**12 TOTAL PACKETS**

**Honey Lemon**

- CM20324 Front Carton

0067-7923-02

M U L T I - S Y M P T O M F L U R E L I E F

**NEW**

USE ONLY AS DIRECTED

**gsk**

# THERAFLU

**FLU RELIEF  
MAX STRENGTH\***

## **6 x DAYTIME**

Acetaminophen Pain Reliever / Fever Reducer  
Dextromethorphan HBr Cough Suppressant

## **6 x NIGHTTIME**

Acetaminophen Pain Reliever / Fever Reducer  
Chlorpheniramine Maleate Antihistamine  
Dextromethorphan HBr Cough Suppressant

**Hot liquid therapy** that relieves:

- / Fever / Body ache / Headache
- / Sore throat pain / Cough
- / Runny nose (Nighttime only)

**6 DAYTIME PACKETS  
6 NIGHTTIME PACKETS  
12 TOTAL PACKETS**

**Honey Lemon**



**THERAFLU FLU RELIEF MAX STRENGTH DAYTIME NIGHTTIME  
COMBO PACK**

acetaminophen, dextromethorphan hbr, and acetaminophen, chlorpheniramine maleate,

dextromethorphan hbr kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-7923
---------------------	----------------	---------------------------	---------------

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7923-02	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	06/15/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CARTON	6
Part 2	1 CARTON	6

### Part 1 of 2

## THERAFLU FLU RELIEF MAX STRENGTH DAYTIME

acetaminophen, dextromethorphan hbr powder

### Product Information

<b>Item Code (Source)</b>	NDC:0067-7921
---------------------------	---------------

<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	1000 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 230V73Q5G9)	
<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>SOYBEAN LECITHIN</b> (UNII: 1DI56QDM62)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)	

### Product Characteristics

<b>Color</b>	white (to off white, yellow, beige, and brown color)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY (Lemon)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7921-02	6 in 1 CARTON; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/15/2022	

## Part 2 of 2

### THERAFLU FLU RELIEF MAX STRENGTH NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr powder

### Product Information

<b>Item Code (Source)</b>	NDC:0067-7922
<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	1000 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

### 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>SOYBEAN LECITHIN</b> (UNII: 1DI56QDM62)
<b>SUCROSE</b> (UNII: C151H8M554)
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)

<b>Product Characteristics</b>			
<b>Color</b>	white (white to off-white, yellow, beige, and brown color)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY (lemon)	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7922-02	6 in 1 CARTON; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/15/2022	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/15/2022	

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