

**THERAFLU SEVERE COLD RELIEF DAYTIME- acetaminophen,  
dextromethorphan hbr powder, for solution  
Haleon US Holdings LLC**

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***Drug Facts***

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

Acetaminophen 500 mg

Dextromethorphan HBr 20 mg

***Purposes***

Pain reliever/Fever reducer

Cough suppressant

***Uses***

- temporarily relieves these symptoms due to a cold:
  - o minor aches and pains
  - o minor sore throat pain
  - o headache
  - o 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 a 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 doctor before use if you have**

- liver disease
- 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

### **Stop use and ask a doctor if**

- 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.
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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 20 mg
- **phenylketonurics:** contains phenylalanine 20 mg per packet
- store at controlled room temperature 20<sup>o</sup>-25<sup>o</sup>C (68<sup>o</sup> - 77<sup>o</sup>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, maltodextrin, natural and artificial flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

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

**1-855-328-5259**

### **Additional information**

**READ ALL WARNINGS 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 THERAFLUPACKET IS TORN OR BROKEN**

**1-855-328-5259**

**Distributed by: Haleon, Warren, NJ 07059**

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**Principal Display**

**NEW FORMULA**

**HALEON**

**THERAFLU**

**SEVERE COLD RELIEF**

**Acetaminophen - Pain Reliever/Fever Reducer**

**Dextromethorphan HBr - Cough Suppressant**

**DAYTIME FORMULA**

**Hot liquid therapy that relieves:**

**/ Cough**

**/ Sore throat pain**

**/ Head and body ache**

**/ Fever**

**Honey Lemon Flavor**

**6 PACKETS**



## THERAFLU SEVERE COLD RELIEF DAYTIME

acetaminophen, dextromethorphan hbr powder, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-0100
<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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

## Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

## Product Characteristics

Color	WHITE (to off white, yellow and brown)	Score	
Shape		Size	
Flavor	HONEY (Lemon)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0100-06	6 in 1 CARTON	12/01/2023	
1		1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0067-0100-99	1000 in 1 CONTAINER	01/01/2025	
2		1 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	12/01/2023	

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