

**THERAFLU SEVERE COLD RELIEF CHEST CONGESTION DAYTIME-  
acetaminophen, dextromethorphan hbr, guaifenesin syrup  
Haleon US Holdings LLC**

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**Drug Facts**

***Active ingredients (in each 30 mL)***

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

***Purposes***

Pain reliever/Fever reducer

Cough suppressant

Expectorant

***Uses***

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

***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 a 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
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis 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 or cough 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**
  - measure the dose correctly using the enclosed dosing cup
  - take every 4 hours in dosing cup provided, while symptoms persist
  - do not take more than 5 doses (150 mL) in 24 hours unless directed by a doctor
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Age	Dose
Adults and children 12 years of age and over	30 mL
Children under 12 years of age	do not use

### ***Other information***

- each 30 mL contains: potassium 30 mg, sodium 13 mg
- store at controlled room temperature 20°-25°C (68°-77°F)

### ***Inactive ingredients***

acesulfame potassium, anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, glycerin, maltitol solution, natural and artificial flavors, propylene glycol, purified water, sodium benzoate, sodium citrate

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

**1-855-328-5259**

### **Generic Section**

Distributed by: Haleon, Warren, NJ 07059 Made in Mexico

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### **PEEL BACK HERE**

DO NOT USE IF NECKBAND PRINTED WITH "SEALED FOR SAFETY" IS TORN OR MISSING.

### **Package/Label Principal Display Panel**

MULTI-SYMPTOM **COLD RELIEF**

**THERAFLU**

**SEVERE**

**COLD RELIEF**

**+ CHEST CONFESSION**

**Acetaminophen**

Pain reliever/Fever Reducer

**Dextromethorphan HBr**

Cough Suppressant

**Guaifenesin/** Expectorant

DAYTIME FORMULA

**Powerful formula that relieves:**

/ Chest congestion

/ Thins and loosens mucus

/ Head and body ache

/ Fever

/ Cough

/ Sore throat pain

8.3 FL OZ (245.5 mL)

**Berry Flavor**

**PARENTS:**

Learn about teen medicine abuse

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

MULTI-SYMP TOM COLD RELIEF

HALEON

# THERAFLU

## SEVERE COLD RELIEF

### + CHEST CONGESTION

**Acetaminophen**  
Pain Reliever/Fever Reducer  
**Dextromethorphan HBr**  
Cough Suppressant  
**Guaifenesin / Expectorant**



**Powerful formula that relieves:**

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acetaminophen, dextromethorphan hbr, guaifenesin syrup

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-0104
<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	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

<b>GUAIFENESIN</b> (UNII: 495W7431VQ) (GUAIFENESIN - UNII:495W7431VQ)	<b>GUAIFENESIN</b>	in 30 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 230V73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0104-08	245.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2023	

### 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)