

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

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

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 CONFECTION

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

MULTI-SYMPTOM COLD RELIEF

HALEON

THERAFLU

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COLD RELIEF**

+ CHEST CONGESTION

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**DAYTIME
FORMULA**

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-0104
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
GUAIFENESIN (UNII: 405W7451VQ) (GUAIFENESIN - UNII:405W7451VQ)	GUAIFENESIN	400 mg

GUAFENESIN (UNII: 493W/431VQ) (GUAFENESIN - UNII:493W/431VQ)		GUAFENESIN	in 30 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
MALTITOL (UNII: D65DG142WK)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
Product Characteristics				
Color	RED	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				
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)