# THERAFLU FLU RELIEF MAX STRENGTH NIGHTTIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr syrup Haleon US Holdings LLC

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# **Drug Facts**

# Active ingredients (in each 30 mL)

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
- 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
- measure the dose correctly using the enclosed dosing cup
- adults and children 12 years of age and over: take every 6 hours in dosing cup provided, while symptoms persist
- do not take more than 3 doses (90 mL) in 24 hours unless directed by a doctor
- children under 12 years of age: do not use

#### Other information

- each 30 mL contains: potassium 6 mg, sodium 32 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

### Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, light amber honey, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium gluconate, sucralose, xanthan gum, zinc gluconate

#### Questions or comments?

1-855-328-5259

#### **Additional Information**

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

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

#### LIFT HERE

\*Maximum Strength per 6 hour dose.

PARENTS:Learn about teen medicine abuse

www.StopMedicineAbuse.org

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#### **Principal Display Panel**

NDC 0067-8205-01

**THERAFLU** 

**FLU RELIEF** 

**MAX STRENGTH\*** 

NIGHTTIME

#### Acetaminophen

Pain Reliever/Fever Reducer

**Chlorpheniramine Maleate** 

# Antihistamine

# **Dextromethorphan HBr**

Cough Suppressant

# Powerful fever fighting

formula that relieves:

/ Body ache

/ Headache

/ Sore throat pain

/ Cough

/ Runny nose

# **Honey & Elderberry Flavor**

8.3 FL OZ (245.5 mL)

1001488 Front Bottle Label



# THERAFLU FLU RELIEF MAX STRENGTH NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-8205
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	1000 mg in 30 mL	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII:3U6I01965U)	CHLORPHENIRAMINE MALEATE	4 mg in 30 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)		
GLYCERIN (UNII: PDC6A3C0OX)		
HONEY (UNII: Y9H1V576FH)		
PEG-10 .BETASITOSTERYL ETHER (UNII: B2138XJ83G)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SODIUM GLUCONATE (UNII: R6Q3791S76)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)		

Product Characteristics		
Color		Score
Shape		Size
Flavor	BERRY (Elderberry)	Imprint Code
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067- 8205-01	245.5 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/27/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/27/2022	

# Labeler - Haleon US Holdings LLC (079944263)

Revised: 3/2024 Haleon US Holdings LLC