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

Drug Facts

Theraflu Flu Relief Max Strength Daytime Syrup

Active ingredients (in each 30 mL)

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**
- 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

1. Age	1. Dose
1. adults and children 12 years of age and over	1. 30 mL
1. children under 12 years of age	1. 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?

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

Theraflu Flu Relief Max Strength Nighttime Syrup

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
- 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
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- 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
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- 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
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- measure the dose correctly using the enclosed dosing cup
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- 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

1. Age	1. Dose
1. adults and children 12 years of age and over	1. 30 mL
1. children under 12 years of age	1. 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?

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

Other Safety Information

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.

PARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

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

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

DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 6 HOURS AFTER THE LAST DOSE OF THE DAYTIME PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

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

1-855-328-5259

Distributed by: **GSK Consumer Healthcare**

Warren, NJ 07059

Made in Canada

Principal Display Panel

NDC 0067-8204-01

THERAFLU

FLU RELIEF

MAX STRENGTH*

DAYTIME FORMULA

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Powerful *fever fighting*

formula that relieves:

/ Body ache

/ Headache

/ Sore throat pain

/ Cough

Honey & Elderberry Flavor

8.3 FL OZ (245.5mL)

NDC 0067-8205-01

THERAFLU

FLU RELIEF

MAX STRENGTH*

NIGHTTIME

HELPS YOU REST

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 (245.5mL)

NIGHTTIME

- **2 – 8.3 FL OZ (245.5 mL) BOTTLES TOTAL 16.6 FL OZ (491 mL) USE AS DIRECTED**
- 1001529 Front Carton

THERAFLU FLU RELIEF MAX STRENGTH DAYTIME NIGHTTIME VALUE PACK

acetaminophen, dextromethorphan hbr, and acetaminophen, chlorpheniramine maleate, dextromethorphan hbr kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8206

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8206-01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	06/27/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	245.5 mL
Part 2	1 BOTTLE	245.5 mL

Part 1 of 2

THERAFLU FLU RELIEF MAX STRENGTH DAYTIME

acetaminophen, dextromethorphan hbr syrup

Product Information

Item Code (Source)	NDC:0067-8204
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
HONEY (UNII: Y9H1V576FH)	
PEG-10 .BETA.-SITOSTERYL 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:0067-8204-01	245.5 mL in 1 BOTTLE; 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	06/27/2022	

Part 2 of 2

THERAFLU FLU RELIEF MAX STRENGTH NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr syrup

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

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg in 30 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
HONEY (UNII: Y9H1V576FH)	
PEG-10 .BETA.-SITOSTERYL ETHER (UNII: B2138XJ83G)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
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 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	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