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

Drug Facts

Theraflu Flu Relief Maximum Strength Daytime Caplets

Active ingredients (in each caplet)

Acetaminophen 500 mg

Dextromethorphan HBr 15 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 use more than directed.

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**
- Adults and children 12 years of age and over: take 2 caplets every 6 hours, while symptoms persist
- do not take more than 6 caplets 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. 2 caplets every 6 hours
1. children under 12 years of age	1. do not use

Other information

- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

crospovidone, D&C yellow no. 10 aluminum lake, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl

alcohol, povidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

call **1-855-328-5259**

Theraflu Flu Relief Maximum Strength Nighttime Caplets

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan HBr 15 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
- 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 a MAO, 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- 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,

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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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- do not take more than 6 caplets 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. 2 caplets every 6 hours
1. children under 12 years of age	1. do not use

Other information
- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

crospovidone, FD&C blue no. 2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, sodium starch

glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-855-328-5259

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

*Maximum Strength per 6 hour dose.

TAMPER-EVIDENT FEATURE: THERAFLU FLU RELIEF MAX STRENGTH CAPLETS ARE SEALED IN BLISTER PACKETS. USE ONLY IF THE INDIVIDUAL SEAL IS UNBROKEN.

READ ALLWARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

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.

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

Distributed by: **GSK Consumer Healthcare**

Warren, NJ 07059

B-0630-770771-10 REV A

Principal Display Panel

NDC 0067-8161-01

THERAFLU

FLU RELIEF

MAX STRENGTH*

MULTI-SYMPTOM FLU RELIEF

Powerful *fever fighting*formula that relieves:

/ Body ache / Headache

/ Sore throat pain / cough

/ Runny nose (Nighttime only)

DAYTIME

Acetaminophen

Pain Reliever / Fever Reducer

Dextromethorphan HBr

Cough Suppressant

NIGHTTIME

Acetaminophen

Pain Reliever / Fever Reducer

Chlorpheniramine Maleate

Antihistamine

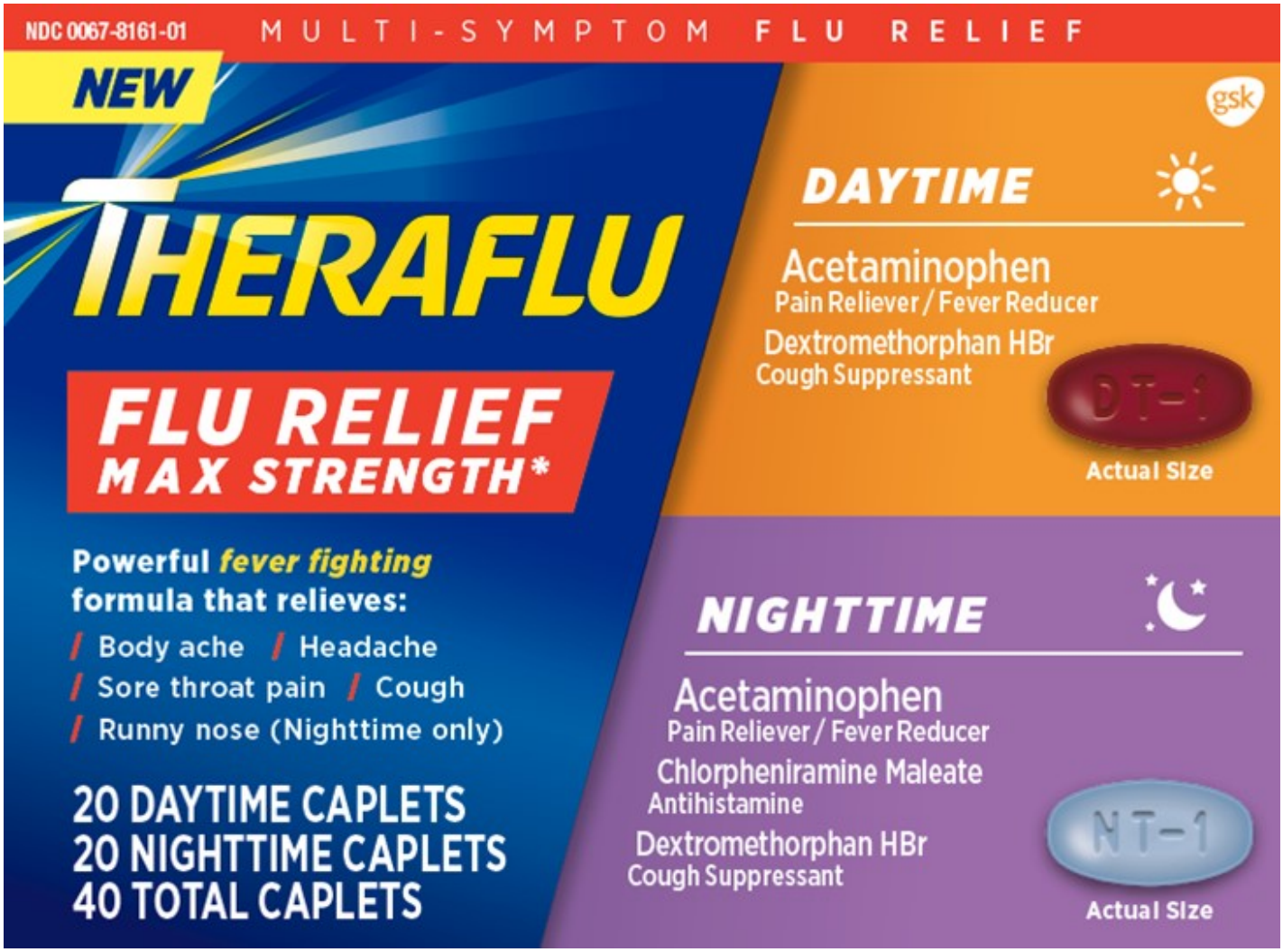
Dextromethorphan HBr

Cough Suppressant

20 DAYTIME CAPLETS

20 NIGHTTIME CAPLETS

40 TOTAL CAPLETS



THERAFLU FLU RELIEF MAXIMUM STRENGTH DAYTIME NIGHTTIME COMBO PACK

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8161

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8161-01	1 in 1 CARTON; Type 0: Not a Combination Product	06/27/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	20
Part 2	1 BLISTER PACK	20

Part 1 of 2

THERAFLU FLU RELIEF MAX DAYTIME

acetaminophen, dextromethorphan hbr tablet

Product Information	
Item Code (Source)	NDC:0067-8162
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	DT;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8162-01	20 in 1 BLISTER PACK; 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	

Part 2 of 2

THERAFLU FLU RELIEF MAX NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr tablet

Product Information

Item Code (Source)	NDC:0067-8163
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	NT;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8163-01	20 in 1 BLISTER PACK; 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	07/15/2015	

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