THERAFLU SEVERE COLD RELIEF- acetaminophen, dextromethorphan hbr, diphenphydramine hcl, guaifenesin
Haleon US Holdings LLC

Drug Facts

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

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Purposes **(Daytime)**

Pain reliever/Fever reducer

Cough suppressant

Expectorant

Uses **(Daytime)**

- 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 **(Daytime)**

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
- 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* (Daytime)**

- **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* (Daytime)**

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

***Inactive ingredients* (Daytime)**

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?* (Daytime)**

1-855-328-5259

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

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

***Purposes* (Nighttime)**

Pain reliever/Fever reducer

Antihistamine/Cough suppressant

***Uses* (Nighttime)**

- temporarily relieves these symptoms due to a cold:
    - minor aches and pains
    - minor sore throat pain
    - headache

- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation

- temporarily reduces fever

Warnings **(Nighttime)**

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.
- with any other product containing diphenhydramine, even one used on the skin
- 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
- 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 sedatives or tranquilizers
- taking the blood thinning drug warfarin

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

- 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 **(Nighttime)**

- **do not use more than directed**
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- 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
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Other information **(Nighttime)**

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

***Inactive ingredients* (Nighttime)**

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?* (Nighttime)**

1-855-328-5259

Additional Information

DO NOT TAKE THE DAYTIME AND NIGHTTIME PRODUCTS AT THE SAME TIME. DO NOT TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 4 HOURS AFTER THE LAST DOSE OF THE DAYTIME PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME OR TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

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

***Temporarily controls cough to help you rest. This is not a sleep aid.**

Principal Display Panel (Day/Night Combination)

MULTI-SYMPTOM **COLD RELIEF**

NEW FORMULA

VALUE PACK

DAYTIME FORMULA

SEVERE COLD RELIEF

MULTI-SYMPTOM COLD RELIEF

NEW FORMULA

THERAFLU

SEVERE COLD RELIEF + CHEST CONGESTION

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**

SEVERE COLD RELIEF

HELPS YOU REST*

MULTI-SYMPTOM COLD RELIEF

NEW FORMULA

THERAFLU

SEVERE COLD RELIEF NIGHTTIME

Acetaminophen

Pain Reliever/Fever Reducer

Diphenhydramine HCl

Antihistamine/Cough Suppressant

HELPS YOU REST*

Powerful formula that relieves:

/ Cough

/ Sore throat pain

/ Head and body ache

/ Fever

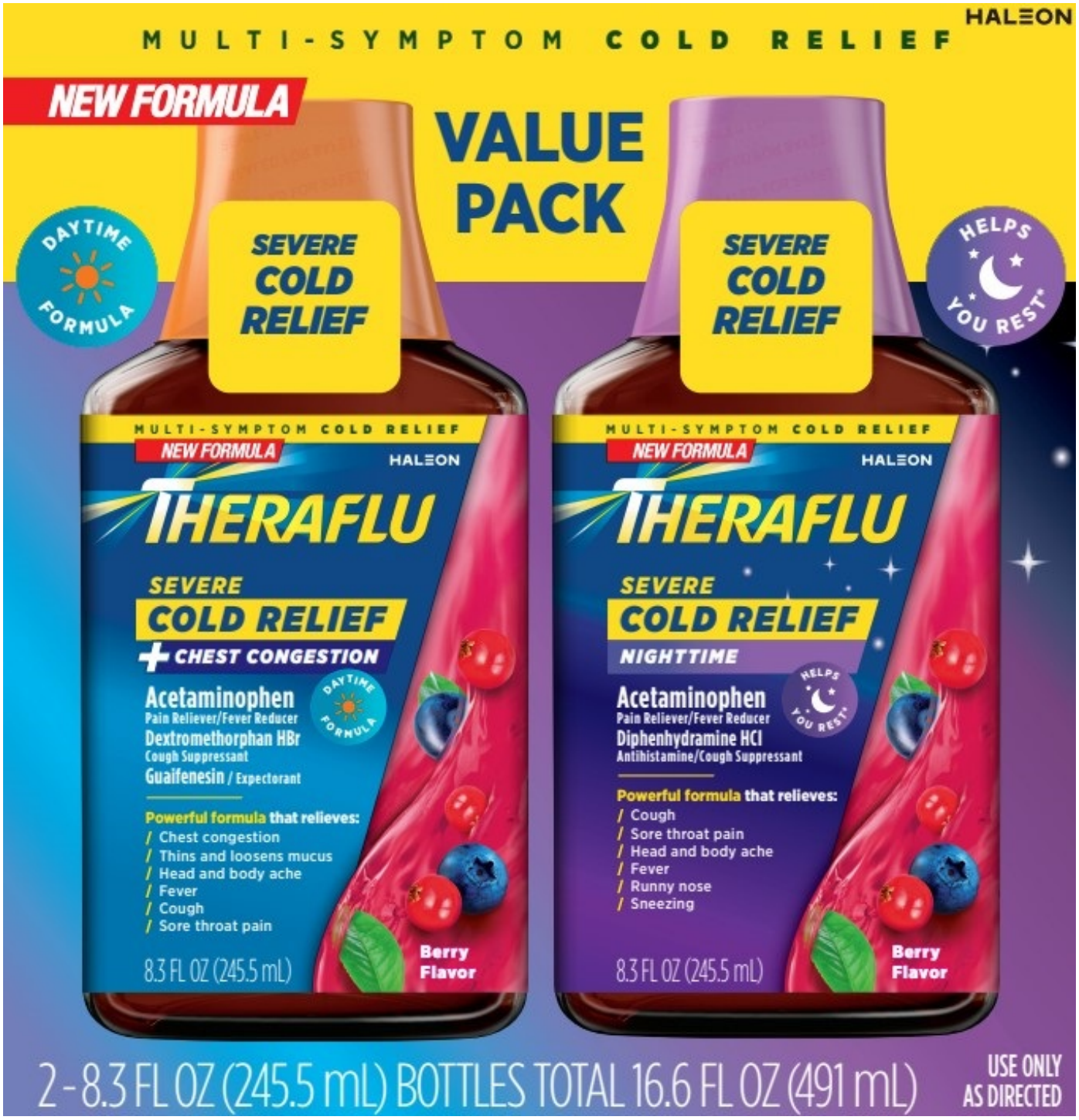
/ Runny nose

/ Sneezing

8.3 FL OZ (245.5 mL) **Berry Flavor**

2-8.3 FL OZ (245.5 mL) BOTTLES TOTAL 16.6 FL OZ (491 mL)

USE ONLY AS DIRECTED



THERAFLU SEVERE COLD RELIEF

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-0107

Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0107-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	02/01/2024	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	0 BOTTLE	1 mL
Part 2	0 BOTTLE	1 mL

Part 1 of 2

THERAFLU SEVERE COLD RELIEF CHEST CONGESTION DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin syrup

Product Information	
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: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2023	

Part 2 of 2

THERAFLU SEVERE COLD RELIEF NIGHTTIME

acetaminophen, diphenhydramine hcl syrup

Product Information

Item Code (Source)	NDC:0067-0105
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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg 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:0067-0105-08	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	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/2024	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 10/2024 Haleon US Holdings LLC