THERAFLU MULTI-SYMPTOM SEVERE COLD AND THERAFLU NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl
Haleon US Holdings LLC

Drug Facts

Theraflu Multi-Symptom Severe Cold

Active ingredients (in each packet)

Acetaminophen 500 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain Reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - nasal and sinus congestion
  - cough due to minor throat and bronchial irritation
- 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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

When using this product

- **do not exceed recommended dosage**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion 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**
- take every 4 hours, while symptoms persist. Do not take more than 6 packets in 24 hours unless directed by a doctor.

1. Age	1. Dose
1. adults and children 12 years of age and over	1. one packet
1. children under 12 years of age	1. do not use

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other information

- **each packet contains:**potassium 10 mg, sodium 19 mg
- **phenylketonurics:**contains phenylalanine 20 mg per packet
- store at controlled room temperature 20°-25°C (68°-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

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

Theraflu Nighttime Severe Cold & Cough

Active ingredients (in each packet)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

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

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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not exceed recommended dosage**
- 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

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion 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**
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

1. Age	1. Dose
1. adults and children 12 years of age and over	1. one packet
1. children under 12 years of age	1. do not use

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other information

- **each packet contains:**potassium 10 mg, sodium 23 mg
- **phenylketonurics:**contains phenylalanine 13 mg per packet
- store at controlled room temperature 20°-25°C (68°-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

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

Additional Information

DO NOT TAKE THE MULTI-SYMPTOM AND NIGHTTIME PRODUCTS AT THE SAME TIME. DO NOT 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 SEALED THERAFLU PACKET IS TORN OR BROKEN.

1-855-328-5259

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READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

DO NOT TAKE THE MULTI-SYMPTOM 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 MULTI-SYMPTOM PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

Principal Display Panel

NDC 0067-7919-12

THERAFLU

MULTI-SYMPTOM SEVERE COLD

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***

TEA INFUSIONS

GREEN TEA & HONEY LEMON FLAVORS

MULTI-SYMPTOM 6 PACKETS

NIGHTTIME

SEVERE COLD & COUGH

Acetaminophen

Pain Reliever/Fever Reducer

Diphenhydramine HCl

Antihistamine/Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***
- ***Runny Nose***
- ***Sneezing***

HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS

NIGHTTIME 6 PACKETS

USE AS DIRECTED

12 TOTAL PACKETS

gsk

13469

Principal Display Panel

NDC 0067-8200-01

THERAFLU

MULTI-SYMPTOM SEVERE COLD

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***

TEA INFUSIONS

GREEN TEA & HONEY LEMON FLAVORS

MULTI-SYMPTOM 18 PACKETS

NIGHTTIME

SEVERE COLD & COUGH

Acetaminophen

Pain Reliever/Fever Reducer

Diphenhydramine HCl

Antihistamine/Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***
- ***Runny Nose***
- ***Sneezing***

HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS

NIGHTTIME 6 PACKETS

USE AS DIRECTED

24 TOTAL PACKETS

gsk

13471

THERAFLU MULTI-SYMPTOM SEVERE COLD AND THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-7919

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7919-12	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/01/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	1422 mL

Part 2	6 PACKET	1422 mL

Part 1 of 2

THERAFLU MULTI-SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-6426
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 237 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY (GREEN TEA & HONEY LEMON FLAVORS)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:0067-6426-06	6 in 1 CARTON		
1	NDC:0067-6426-01	237 mL in 1 PACKET; 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	07/01/2014	

Part 2 of 2

THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-7918
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 237 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON (HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7918-06	6 in 1 CARTON		
1	NDC:0067-7918-01	237 mL in 1 PACKET; 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	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2016	

THERAFLU MULTI-SYMPTOM SEVERE COLD AND THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-8200

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8200-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	09/01/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	18 PACKET	4266 mL
Part 2	6 PACKET	1422 mL

Part 1 of 2

THERAFLU MULTI-SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-6426
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 237 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY (GREEN TEA & HONEY LEMON FLAVORS)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-6426-	6 in 1 CARTON		

1	06	6 in 1 CARTON		
1	NDC:0067-6426-01	237 mL in 1 PACKET; 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	07/01/2014	

Part 2 of 2

THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-7918
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 237 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON (HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7918-06	6 in 1 CARTON		
1	NDC:0067-7918-01	237 mL in 1 PACKET; 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	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2016	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC