

**THERAFLU EXPRESSMAX DAYTIME NIGHTTIME VALUE PACK- acetaminophen, dextromethorphan hbr, phenylephrine hcl and acetaminophen, diphenhydramine hcl, phenylephrine hcl  
Haleon US Holdings LLC**

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**Drug Facts**

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

Acetaminophen 650 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**
- 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

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 35 mg, sodium 17 mg
- store at controlled room temperature 20-25°C (68-77°F)

***Inactive ingredients***

acesulfame potassium, anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

***Questions?***

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

**Theraflu ExpressMax Nighttime Severe Cold & Cough**

**Drug Facts**

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

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 a MAO, 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.

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ask a health professional before use.

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- do not take more than 5 doses (150 mL) in 24 hours unless directed by a doctor

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 35 mg, sodium 17 mg
- store at controlled room temperature 20-25°C (68-77°F)

### **Inactive ingredients**

acesulfame potassium, anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

### **Questions?**

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

### **Other Safety Information**

DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME OR 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.

**PARENTS:** Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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

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Warren, NJ 07059

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### **Principal Display Panel**

**NDC 0067-8125-16**

***THERAFLU***

***ExpressMax***

**DAYTIME**

**SEVERE COLD & COUGH**

**BERRY FLAVOR**

**ACETAMINOPHEN**

PAIN RELIEVER/FEVER REDUCER

**DEXTROMETHORPHAN HBr**

COUGH SUPPRESSANT

**PHENYLEPHRINE HCl**

NASAL DECONGESTANT

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

8.3 FL OZ (245.5mL)

Alcohol Free

**DAYTIME**

***THERAFLU***

***ExpressMax***

**NIGHTTIME**

**SEVERE COLD & COUGH**

**BERRY FLAVOR**

**ACETAMINOPHEN**

PAIN RELIEVER/FEVER REDUCER

**DIPHENHYDRAMINE HCl**

ANTIHISTAMINE/COUGH SUPPRESSANT

**PHENYLEPHRINE HCl**

NASAL DECONGESTANT

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

8.3 FL OZ (245.5mL)

Alcohol Free

**NIGHTTIME**

- **2 - 8.3 FL OZ (245.5 mL) BOTTLES TOTAL 16.6 FL OZ (491 mL)** Use Only As Directed

**VALUE PACK**

**Warming Relief FORMULA**

**THERAFLU ExpressMax**

**SEVERE COLD & COUGH**

**DAYTIME**

Acetaminophen  
Pain Reliever/Fever Reducer  
Dextromethorphan HBr  
Cough Suppressant  
Phenylephrine HCl  
Nasal Decongestant

➤ Cough ➤ Nasal Congestion  
➤ Sore Throat Pain ➤ Fever  
➤ Headache ➤ Body Ache

**BERRY FLAVOR**

8.3 FL OZ (245.5 mL) Alcohol Free

**DAYTIME**

**NIGHTTIME**

**SEVERE COLD & COUGH**

**NIGHTTIME**

Acetaminophen  
Pain Reliever/Fever Reducer  
Diphenhydramine HCl  
Antihistamine/Cough Suppressant  
Phenylephrine HCl  
Nasal Decongestant

➤ Cough ➤ Nasal Congestion  
➤ Sore Throat Pain ➤ Fever  
➤ Headache ➤ Body Ache  
➤ Runny Nose

**BERRY FLAVOR**

8.3 FL OZ (245.5 mL) Alcohol Free

**NIGHTTIME**

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

Use Only As Directed

**Principal Display Panel**

**NDC 0067-8127-08**

**THERAFLU**

**ExpressMax**

**DAYTIME**

**SEVERE COLD & COUGH**

**BERRY FLAVOR**



**ACETAMINOPHEN**

PAIN RELIEVER/FEVER REDUCER

**DEXTROMETHORPHAN HBr**

COUGH SUPPRESSANT

**PHENYLEPHRINE HCl**

NASAL DECONGESTANT

• **Cough** • **Nasal Congestion**

• **Sore Throat Pain** • **Fever**

• **Headache** • **Body Ache**

**8.3 FL OZ (245.5mL)**

Alcohol Free

NDC 0067-8127-08

gsk

# **THERAFLU**

## **ExpressMax**

**SEVERE  
COLD & COUGH**

**DAYTIME**



**Acetaminophen**

Pain Reliever/Fever Reducer

**Dextromethorphan HBr**

Cough Suppressant

**Phenylephrine HCl**

Nasal Decongestant

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



**BERRY FLAVOR**

**8.3 FL OZ (245.5 mL)**

**Alcohol Free**

**Principal Display Panel**

**NDC 0067-8129-08**

**THERAFLU**

**ExpressMax**

**NIGHTTIME**

**SEVERE COLD & COUGH**

**BERRY FLAVOR**

**ACETAMINOPHEN**

PAIN RELIEVER/FEVER REDUCER

**DIPHENHYDRAMINE HCl**

ANTIHISTAMINE/COUGH SUPPRESSANT

**PHENYLEPHRINE HCl**

NASAL DECONGESTANT

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

**8.3 FL OZ (245.5mL)**

Alcohol Free

NDC 0067-8129-08



# THERAFLU

## ExpressMax

**SEVERE  
COLD & COUGH**

**NIGHTTIME**



**Acetaminophen**

Pain Reliever/Fever Reducer

**Diphenhydramine HCl**

Antihistamine/Cough Suppressant

**Phenylephrine HCl**

Nasal Decongestant

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



**BERRY FLAVOR**

**8.3 FL OZ (245.5 mL)**

Alcohol Free

### THERAFLU EXPRESSMAX DAYTIME NIGHTTIME VALUE PACK

acetaminophen, dextromethorphan hbr, phenylephrine hcl and acetaminophen, diphenhydramine hcl, phenylephrine hcl kit

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-8125
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#### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:0067-8125-16	1 in 1 CARTON; Type 0: Not a Combination Product	07/15/2015	

### 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 EXPRESSMAX DAYTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, phenylephrine hcl syrup

### Product Information

Item Code (Source) NDC:0067-8127

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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 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)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8127-08	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	07/15/2015	

### Part 2 of 2

## THERAFLU EXPRESSMAX NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl syrup

### Product Information

<b>Item Code (Source)</b>	NDC:0067-8129
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 30 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8129-08	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	07/15/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/15/2015	

**Labeler** - Haleon US Holdings LLC (079944263)