THERAFLU EXPRESSMAX DAYTIME NIGHTTIME VALUE PACK- acetaminophen, dextromethorphan hbr, phenylephrine hcl and acetaminophen, diphenhydramine hcl, phenylephrine hcl
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Theraflu® ExpressMax™ Daytime Severe Cold & Cough

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 last 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

Age	Dose
adults and children 12 years of age and over	30 mL
children under 12 years of age	do not use

Other information

- **each 30 mL contains**: potassium 25 mg, sodium 17 mg
- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

acesulfame potassium, alcohol, 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 or Comments?

call **1-800-452-0051**

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 and 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.

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

Age	Dose
adults and children 12 years of age and over	30 mL
children under 12 years of age	Do not use

Other information

- **each 30 mL contains**: potassium 25 mg, sodium 16 mg
- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

acesulfame potassium, alcohol, 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?

1-800-452-0051

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 DAYTIME PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

Principal Display Panel

NDC 0067-8125-16

THERAFLU®

ExpressMax™

VALUE PACK

Use Only as Directed

Alcohol Content: 10%

DAYTIME

NIGHTTIME

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

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

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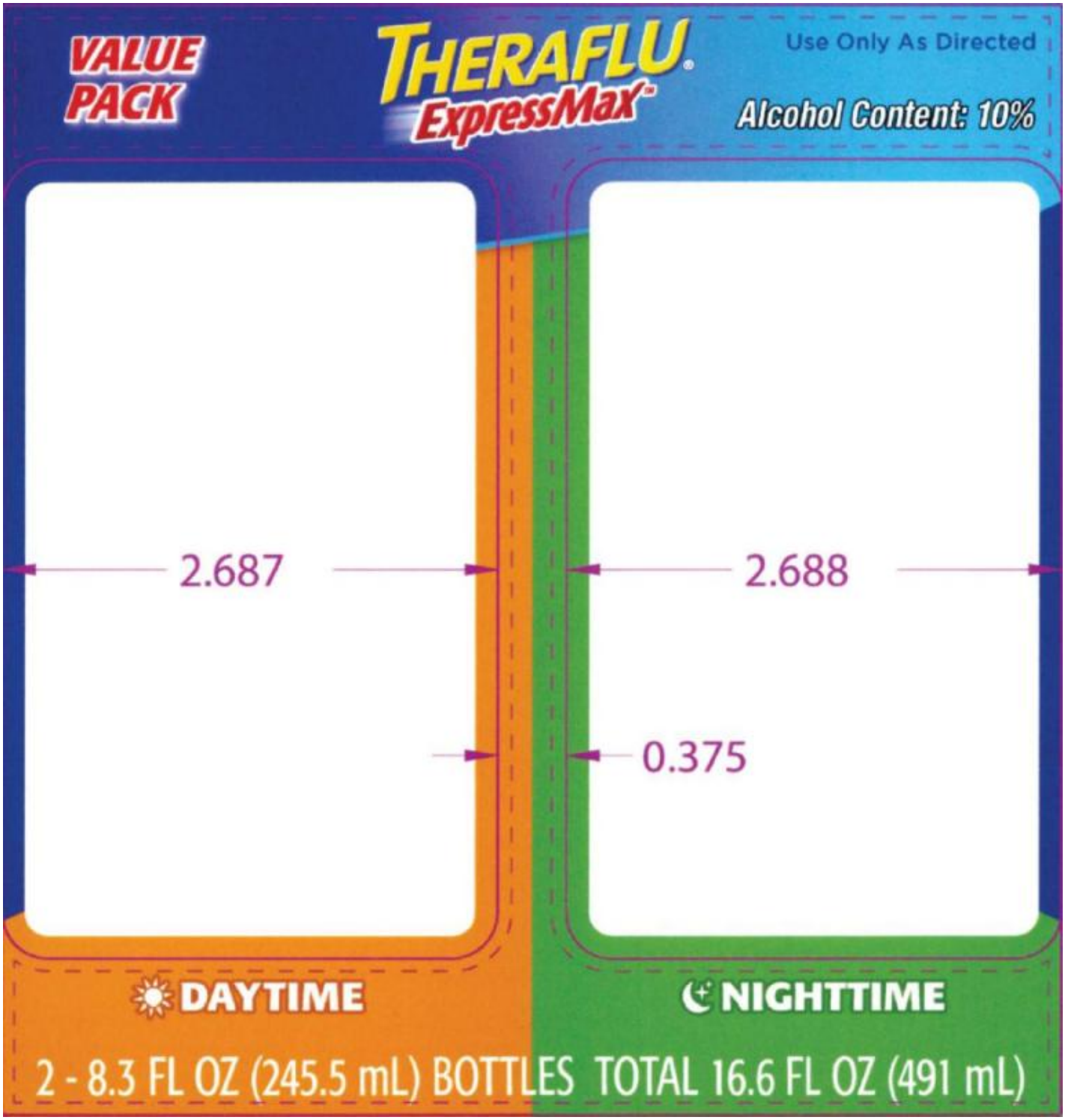

NDC 0067-8127-08

THERAFLU®

ExpressMax™

DAYTIME

BERRY FLAVOR

SEVERE COLD & COUGH

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

DEXTROMETHORPHAN HBr-COUGH SUPPRESSANT

PHENYLEPHRINE HCl-NASAL DECONGESTANT

•NASAL CONGESTION • SORE THORAT PAIN •COUGH

•BODY ACHE • HEADACHE •FEVER

8.3 FL OZ (245.5mL)

Alcohol Content: 10%

NDC 0067-8129-08

THERAFLU®

ExpressMax™

NIGHTTIME

BERRY FLAVOR

SEVERE COLD & COUGH

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

DEXTROMETHORPHAN HBl-ANTIHISTAMINE/COUGH SUPPRESSANT

PHENYLEPHRINE HCl-NASAL DECONGESTANT

•NASAL CONGESTION • HEADACHE • SORE THORAT PAIN

•RUNNY NOSE • BODY ACHE • COUGH •FEVER

8.3 FL OZ (245.5mL)

Alcohol Content: 10%

THERAFLU EXPRESSMAX DAYTIME NIGHTTIME VALUE PACK

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8125

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End 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: 9D2RTI9KYH) (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)	
ALCOHOL (UNII: 3K9958V90M)	
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 (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	

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:0067-8127-08	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 final	part341	07/15/2015	

Part 2 of 2

THERAFLU EXPRESSMAX NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl syrup

Product Information	
Item Code (Source)	NDC:0067-8129
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
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 (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	

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:0067-8129-08	245.5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/15/2015	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/15/2015	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 3/2016 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC