THERAFLU EXPRESSMAX NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, diphenhydramine hcl, phenylephrine hcl syrup
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

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 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**
- 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 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?

1-800-452-0051

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 THORAT PAIN • FEVER

• HEADACHE • BODY ACHE

• RUNNY NOSE

8.3 FL OZ (245.5mL)

Alcohol Free

*** Maximum Strength per 4 hour dose.**

DO NOT USE IF NECKBAND PRINTED WITH “SEALED FOR SAFETY” IS TORN OR MISSING

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13273

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acetaminophen, diphenhydramine hcl, phenylephrine hcl syrup

Product Information			
Product Type	HUMAN OTC DRUG	**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)	
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

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	07/15/2015	

Marketing Information

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)