THERAFLU EXPRESSMAX SEVERE COLD AND FLU CAPLETS- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, coated
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 caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

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
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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, chromic bronchitis 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**
- adults and children 12 years of age and over: take 2 caplets every 4 hours, while symptoms persist. Do not take more than 10 caplets in 24 hours unless directed by a doctor.
- children under 12 years of age: do not use

Other information

- **each caplet contains**: sodium 5 mg
- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

benzoic acid, carmine, croscarmellose sodium, crospovidone, ethanol, ferric oxide yellow, flavors, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 60, polysorbate 80, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, titanium dioxide

Questions or Comments?

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

Package/Label Principal Display Panel

NDC 0067-8145-01

Theraflu®*Expressmax*™

SEVERE COLD AND FLU

NEW!

WARMING RELIEF FORMULA

ACETAMINOPHEN- PAIN RELIEVER/ FEVER REDUCER

DEXTROMETHORPHAN HBr- COUGH SUPPRESSANT

GUAIFENESIN- EXPECTORANT

PHENYLEPHRINE HCl- NASAL DECONGESTANT

- BODY ACHE
- FEVER
- CHEST CONGESTION
- NASAL CONGESTION
- HEADACHE

- COUGH
- SORE THROAT PAIN

20 COATED CAPLETS

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

*Maximum Strength per 4 hour dose.

TAMPER EVIDENT FEATURE:

THERAFLU® EXPRESSMAX™ CAPLETS ARE SEALED IN BLISTER PACKETS. USE ONLY IF THE INDIVIDUAL SEAL IS UNBROKEN.

Read all warnings and directions on carton before use. Keep carton for reference. Do not discard.

Distributed by: **GSK Consumer Healthcare**, Warren, NJ 07059

THERAFLU EXPRESSMAX SEVERE COLD AND FLU CAPLETS

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8145
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	10 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARMINIC ACID (UNII: CID8Z8N95N)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
ALCOHOL (UNII: 3K9958V90M)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	**Score**	no score
Shape	OVAL (Capsule shaped)	**Size**	19mm
Flavor	MINT	**Imprint Code**	IL5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8145-01	2 in 1 CARTON	07/17/2017	
1		10 in 1 BLISTER PACK; 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	07/17/2017	

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

Registrant - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC. (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
Mallinckrodt, Inc.		097722284	API MANUFACTURE(0067-8145)

Establishment

Name	Address	ID/FEI	Business Operations
DIVI's Laboratories Limited		918598199	API MANUFACTURE(0067-8145)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918457644	API MANUFACTURE(0067-8145)

Revised: 6/2017 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC.