THERAFLU EXPRESSMAX NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated
Haleon US Holdings LLC

Drug Facts

Active ingredient

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purpose

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 lever 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**
- 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

- store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients

benzoic acid, croscarmellose sodium, ethanol, FD&C blue no.2 aluminum lake, ferrosoferric oxide, flavors, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 60, polysorbate 80, povidone, pregelatinized starch, propylene glycol, silicone dioxide, stearic acid, sucralose, titanium dioxide

Questions or comments?

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

Principal Display Panel

NDC 0067-8137-20

Theraflu ®Express Max ®

NIGHTTIME

SEVERE COLD & COUGH

WARMING RELIEF™ FORMULA

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

DIPHENHYDRAMINE HCl – ANTIHISTAMINE/COUGH SUPPRESSANT

PEHNYLEPHRINE HCl – NASAL DECONGESTANT

- NASAL CONGESTION • SORE THROAT • FEVER • BODY ACHE
- RUNNY NOSE • HEADACHE • COUGH • SNEEZING

20 COATED CAPLETS

*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

62000000010602

THERAFLU EXPRESSMAX NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8137

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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	blue	**Score**	no score
Shape	OVAL (caplet)	**Size**	18mm
Flavor	MINT	**Imprint Code**	1143N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8137-20	2 in 1 CARTON	07/05/2016	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:0067-8137-10	1 in 1 CARTON	06/08/2017	
2		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 Drug	M012	07/05/2016	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 3/2024 Haleon US Holdings LLC