

THERAFLU EXPRESSMAX SEVERE COLD AND FLU SYRUP- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl syrup
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 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, chronic 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**
- 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 30 mg, sodium 14 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 or Comments?

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

Package/Label Principal Display Panel

NDC 0067-8132-08

Theraflu® *Expressmax*™

SEVERE COLD AND FLU

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

ALCOHOL FREE

BERRY FLAVOR 8.3 FL OZ (245.5 mL)

- **PARENTS:**
- Learn about teen medicine abuse
- www.StopMedicineAbuse.org
- *Maximum Strength per 4 hour dose.
- Distributed by: **GSK Consumer Healthcare**, Warren, NJ 07059
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*Maximum Strength per 4 hour dose.

SEVERE COLD & FLU

BERRY FLAVOR

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ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER
DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT
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- BODY ACHE • FEVER • CHEST CONGESTION
- NASAL CONGESTION • HEADACHE • COUGH
- SORE THROAT PAIN

8.3 FL OZ (245.5 mL) *Alcohol Free*

12265

: 366F7 L9 F1

THERAFLU EXPRESSMAX SEVERE COLD AND FLU SYRUP

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl syrup

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0067-8132 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 400 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| 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) | |

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:0067-8132-08 | 1 in 1 BOTTLE; Type 0: Not a Combination Product | 07/07/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 07/07/2017 | |

Revised: 3/2024

Haleon US Holdings LLC