

SEVERE COLD AND FLU RELIEF DAYTIME- acetaminophen, dextromethorphan hbr, guaifenesin phenylephrine hcl liquid
The Kroger Co.

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

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
 - nasal and sinus congestion
 - minor sore throat
 - headache
 - cough due to minor throat and bronchial irritation
- temporarily reduces fever
- help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough 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

- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen
- in a child under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough 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 use more than directed.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse, or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with a 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 (1-800-222-1222) right away. Quick 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**
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- mL= milliliter
- keep dosing cup with product
- dose as follows or as directed by a doctor
- adults and children 12 years and over : 30 mL every 4 hours while symptoms last
- children under 12 years of age: do not use

Other information

- **each 30 mL contains:** potassium 20 mg, sodium 18 mg
- store between 20-25°C (68-77°F)

Inactive ingredients

acesulfame potassium, citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

Principal Display Panel

COMPARE TO the active ingredients of THERAFLU® EXPRESSMAX® SEVERE COLD & FLU *See back panel

Flu Relief Maximum Strength

DAYTIME • SEVERE COLD & FLU

Acetaminophen 650 mg, Pain Reliever/Fever Reducer

Dextromethorphan HBr 20 mg, Cough Suppressant/

Guaifenesin 400 mg Expectorant/

Phenylephrine HCl 10 mg Nasal decongestant

Relieves

- Body ache
- Fever
- Chest congestion
- Nasal congestion

- Headache
- Cough
- Sore throat pain

For ages 12 years and over

Alcohol Free

FL OZ (mL)

Berry Flavor

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

*THERAFLU® IS A REGISTERED TRADEMARK OF GSK CONSUMER HEALTHCARE,
PHILADELPHIA, PA 19112. GSK CONSUMER HEALTHCARE IS NOT AFFILIATED WITH THE
KROGER CO. OR THIS PRODUCT

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

www.kroger.com

Product Label

COMPARE TO the active ingredients in THERAFLU® EXPRESSMAX® SEVERE COLD & FLU *See back panel

NDC 30142-716-08



for ages 12 & over



Maximum Strength

Severe Flu Relief

Acetaminophen 650 mg
Pain Reliever/Fever Reducer
Dextromethorphan HBr 20 mg
Cough Suppressant
Guaifenesin 400 mg
Expectorant
Phenylephrine HCl 10 mg
Nasal Decongestant

RELIEVES
Cough
Headache
Sore Throat Pain
Body Ache & Fever
Chest & Nasal Congestion

Alcohol-Free

Berry Flavor



8.3 FL OZ (245 mL)

PLD-B498A LB007204

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CINCINNATI, OHIO 45202

QUALITY GUARANTEE
800-632-6900 • www.kroger.com



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Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg.....	Cough suppressant
Guaifenesin 400 mg.....	Expectorant
Phenylephrine HCl 10 mg.....	Nasal decongestant

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

Uses

- temporarily relieves these symptoms due to a cold
- minor aches and pains ■ minor sore throat
- nasal and sinus congestion ■ headache
- cough due to minor throat and bronchial irritation
- temporarily reduces fever
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 - with other drugs containing acetaminophen
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- Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:
- skin reddening ■ blisters ■ rash
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Drug Facts (continued)

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 ■ diabetes
- thyroid disease ■ high blood pressure
- trouble urinating due to an enlarged prostate gland
- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product, do not use more than directed.

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- nervousness, dizziness, or sleeplessness occur
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Drug Facts (continued)

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Other information

- each 30 mL contains: potassium 20 mg, sodium 18 mg
- store between 20-25°C (68-77°F)

Inactive ingredients acesulfame potassium, citric acid, EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions or comments? 1-800-632-6900

KROGER Maximum Strength Severe Flu Relief

SEVERE COLD AND FLU RELIEF DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-716
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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 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)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-716-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2018	03/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/31/2018	03/31/2025

Labeler - The Kroger Co. (006999528)

