SEVERE COLD AND COUGH RELIEF DAYTIME- acetaminohpen, dextromethorphan hbr, phenylephrine hcl liquid Family Dollar (FAMILY WELLNESS)

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold
 - minor aches and pains
 - headache
 - nasal and sinus congestion
 - sore throat
 - 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 inclide:

- 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.

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 exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, cough, or nasal congestion 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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. 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 take more than directed (see overdose warning)
- do not take more than 6 doses (180 mL) 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
- adults and children 12 years and over
 - 30 mL every 4 hours
- children under 12 years of age: do not use

Other information

- each 30 mL contains: sodium 16 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

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

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENTS OF THERAFLU® EXPRESSMAX® DAYTIME SEVERE COLD & COUGH*

Severe Cold & Cough

Acetaminophen (Pain Reliever / Fever Reducer)

Dextromethorphan HBr (Cough Suppressant)

Phenylephrine HCI (Nasal Decongestant)

For Relief of:

- Nasal Congestion
- Headache
- Sore Throat Pain
- Cough
- Body Ache
- Fever

BERRY FLAVOR

ALCOHOL 10%

MAXIMUM STRENGTH PER 4 HOUR DOSE

FL OZ (mL)

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

*This product is not manufactured or distributed by GSK Consumer Health, Inc., distributor of Theraflu® ExpressMax® Daytime Severe Cold & Cough.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Product Label

Drug Facts (continued)

doctor or pharmacist.

■ liver disease

thyroid disease

■ high blood pressure

■ with any other drug containing acetaminophen

(prescription or nonprescription). If you are not sure

whether a drug contains acetaminophen, ask a

if you are now taking a prescription monoamine

depression, psychiatric, or emotional conditions,

stopping the MAOI drug. If you do not know if your

prescription drug contains an MAOI, ask a doctor or

heart disease

■ diabetes

■ trouble urinating due to an enlarged prostate gland

■ cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

persistent or chronic cough such as occurs with

oxidase inhibitor (MAOI) (certain drugs for

or Parkinson's disease), or for 2 weeks after

pharmacist before taking this product.

Ask a doctor before use if you have

smoking, asthma, or emphysema

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 occur
- lasts more than 7 days

- new symptoms occur
- cough comes back or occurs with rash or

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Drug Facts (continued)

Uses

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Drug Facts (continued)

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Drug Facts (continued)

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PEEL CORNER FOR MORE DRUG FACTS

SEVERE COLD AND COUGH RELIEF DAYTIME

acetaminohpen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-701
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 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: 230V73Q5G9)		
ALCOHOL (UNII: 3K9958V90M)		
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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319- 701-83	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	06/30/2025

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/30/2020	06/30/2025

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 12/2023 Family Dollar (FAMILY WELLNESS)