

FLU RELIEF THERAPY DAYTIME SEVERE COLD- acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Select Brand Dist.

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 15 mL, 1 tablespoon)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves
 - minor aches and pains
 - headache
 - minor sore throat pain
 - nasal congestion
 - 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 6 doses (12 tablespoons or 180 mL) in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 product 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 or any of the inactive ingredients in this product

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 accompanied by excessive 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 (see overdose warning)**

Stop use and ask a doctor if

- redness or swelling is present
- new symptoms occur
- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with a fever, 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) immediately. 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 in infants**
- **do not exceed recommended dose (see overdose warning)**
- use dosage cup provided
- tbs = tablespoon, mL = milliliter

age	dose
adults and children 12 years and over	2 tablespoons (30 mL) every 4 hours
children 4 to 11 years	do not use unless directed by a doctor
children under 4 years	do not use

Do not take more than 6 doses (12 tablespoons) in 24 hours.

Other information

- each 15 mL contains: **sodium 8 mg**
- store at room temperature

Inactive ingredients

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

Questions or comments?

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

Principal Display Panel**Daytime****Flu Relief Therapy****SEVERE COLD****Pain Reliever / Fever Reducer - Acetaminophen**

Cough Suppressant - Dextromethorphan HBr

Nasal Decongestant - Phenylephrine HCl

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

*Compare to active ingredients in Theraflu®

Distributed by: SELECT BRAND DISTRIBUTORS

Pine Bluff, AR 71603 USA AC (870) 535-3635

Alcohol Content: 10%

Cherry Flavor

FL OZ (mL)

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

Failure to follow the drug facts warnings could result in serious consequences.

PARENTS: Learn about teen medicine abuse www.StopMedicineAbuse.org

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Theraflu® Daytime.

Product Label



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PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

Uses Temporarily relieves

- minor aches and pains • headache
- minor sore throat pain • nasal congestion
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- temporarily reduces fever

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Drug Facts (continued)

MAOI, ask a doctor or pharmacist before taking this product.

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- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have

- liver disease • heart disease • diabetes
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- trouble urinating due to an enlarged prostate gland
- cough accompanied by excessive phlegm (mucus)
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Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product

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Drug Facts (continued)

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Select Brand Flu Relief Therapy Daytime Severe Cold Cherry Liquid

FLU RELIEF THERAPY DAYTIME SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15127-923
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 - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
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: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-923-08	237 in 1 BOTTLE, PLASTIC; 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	08/22/2007	

Labeler - Select Brand Dist. (012578514)

Revised: 10/2014

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