

**FLU AND SEVERE COLD DAYTIME RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid**  
**CVS Pharmacy**

*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.*

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**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 congestion
  - sore throat
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

**Warnings**

**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.

**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.

**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 take more than directed (see overdose warning)
- 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
- 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 at 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**

Daytime Relief

Flu & Severe Cold

Acetaminophen

Pain reliever, fever reducer

Dextromethorphan HBr

Cough suppressant

Phenylephrine HCl

Nasal decongestant

Relief of:

Nasal congestion; cough; fever; body ache; sore throat; headache

Alcohol Content: 10%

Cherry Flavor

For ages 12 & over

FL OZ (mL)

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

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

\*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Theraflu® Daytime Severe Cold & cough.

**Product Label**



Compare to active ingredients in Theraflu® Daytime Severe Cold & Cough\*

Daytime Relief

NDC 59779-926-08

# Flu & Severe Cold

## ACETAMINOPHEN

Pain reliever; Fever reducer

## DEXTROMETHORPHAN HBr

Cough suppressant

## PHENYLEPHRINE HCl

Nasal decongestant

### Relief of:

Nasal congestion;  
Cough; Fever; Body  
ache; Sore throat;  
Headache



Cherry Flavor  
Alcohol content 10%  
For Ages 12 & Over

# 8.3 FL OZ (245 mL)

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

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

#455446



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### Drug Facts

#### Active ingredients (in each 30 mL)

Acetaminophen 650 mg.....Pain reliever/fever reducer  
Dextromethorphan HBr 20 mg.....Cough suppressant  
Phenylephrine HCl 10 mg.....Nasal decongestant

#### Purposes

PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

#### Uses

- temporarily relieves these symptoms due to a cold
- minor aches and pains
- headache
- nasal congestion
- sore throat
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

#### Warnings

**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.

**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

**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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure

### Drug Facts (continued)

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
- thyroid disease
- diabetes
- high blood pressure
- 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

PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

- 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.

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage.

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#### Directions

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- 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 at 20-25°C (68-77°F). Do not refrigerate.

### Drug Facts (continued)

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

#### Questions or comments?

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## CVS Flu & Severe Cold Liquid

# FLU AND SEVERE COLD DAYTIME RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

## Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59779-926

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: 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: 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: 059QF0KOOR)	
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:59779-926-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2015	12/27/2024

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/31/2015	12/27/2024

