

## **SEVERE COLD AND COUGH RELIEF NIGHTTIME- acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid**

**Hy-Vee**

*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**

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

### **Purposes**

#### **Pain reliever/fever reducer**

Antihistamine/Cough suppressant

Nasal decongestant

### **Uses**

- temporarily relieves these symptoms due to a cold
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
  - itchy, watery eyes
  - nasal and sinus congestion
  - itchy of the nose or 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 include:

- skin reddening
- blisters
- rash

**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**

- to make a child sleepy
- 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 diphenhydramine, even one used on skin
- 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
- glaucoma
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- a breathing problem such as emphysema or chronic bronchitis
- 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
- sedatives or tranquilizers

**When using this product**

- **do not exceed recommended dosage**
- alcohol, sedative, and tranquilizers may increase drowsiness
- avoid alcohol drinks
- be careful when driving a motor vehicle or operating machinery
- marked drowsiness may occur
- excitability may occur, especially in children

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occurs
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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) 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 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:** potassium 10 mg
- **each 30 mL contains:** sodium 14 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, flavors, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

### **Questions or comments?**

Call toll free **1-800-289-8343 Monday-Friday 9AM-4PM CST**

### **Principal Display Panel**

\*Compare to the active ingredients of Theraflu® Nighttime Severe Cold & Cough

Severe Cold & Cough Relief

Acetaminophen 650 mg - Pain reliever; Fever Reducer

Diphenhydramine HCl 25 mg - Antihistamine/Cough Suppressant

Phenylephrine HCl 10 mg - Nasal Decongestant

Nighttime

Relieves:

- Cough • Runny Nose & Sneezing
- Itchy Nose or Throat • Itchy, Watery Eyes
- Aches, Fever & Sore Throat • Nasal Congestion
- Ages 12 +

CHERRY FLAVOR

10 % ALCOHOL

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 Novartis Consumer Health, Inc., distributor of Theraflu® Nighttime Severe Cold & Cough.

DISTRIBUTED BY HY-VEE, INC.

WEST DES MOINES, IA 50266

[www.hy-vee.com](http://www.hy-vee.com)

**Product Label**

NDC 42507-317-08

HyVee health

\*COMPARE TO the Active Ingredients of Theraflu® Nighttime Severe Cold & Cough

# Severe Cold & Cough Relief

Acetaminophen 650 mg - Pain Reliever/Fever Reducer  
Diphenhydramine HCl 25 mg - Antihistamine/Cough Suppressant  
Phenylephrine HCl 10 mg - Nasal Decongestant

## Nighttime

**Relieves:**

- Cough
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- Aches, Fever & Sore Throat
- Runny Nose & Sneezing
- Itchy, Watery Eyes
- Nasal Congestion
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CHERRY FLAVOR  
10% ALCOHOL

8.3 FL OZ (245 mL)

PLD-B265B  
LB003447

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DISTRIBUTED BY HY-VEE, INC. SATISFACTION GUARANTEED  
WEST DES MOINES, IA 50266 CALL 1-800-289-8343  
www.hy-vee.com

PLD-B265B  
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### Drug Facts

**Active ingredients (in each 30 mL) Purposes**

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Diphenhydramine HCl 25 mg.....Antihistamine/  
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Phenylephrine HCl 10 mg.....Nasal decongestant

### Uses

- temporarily relieves these symptoms due to a cold
- minor aches and pains
- sore throat
- itchy, watery eyes
- nasal and sinus congestion
- headache
- runny nose
- sneezing

PEEL CORNER FOR MORE DRUG FACTS

PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

- itching of the nose or throat
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

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- 3 or more alcoholic drinks every day while using this product

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- 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** ■ to make a child sleepy

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

### Drug Facts (continued)

ask a doctor or pharmacist.

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- glaucoma
- heart disease
- thyroid disease

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PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

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- 30 mL every 4 hours
- children under 12 years of age: do not use

### Other information

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- each 30 mL contains: sodium 14 mg
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**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?** Call toll free 1-800-289-8343 Monday-Friday 9AM-4PM CST

HyVee Health Severe Cold & Cough Relief Nighttime

## SEVERE COLD AND COUGH RELIEF NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42507-317
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 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: HBR47K3TBD)	
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**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-317-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/30/2015	

