

**NIGHTTIME FLU RELIEF THERAPY SEVERE COLD- acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid**

**AmerisourceBergen (Good Neighbor Pharmacy) 46122**

*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
  - sneezing
  - headache
  - minor sore throat pain
  - itchy, watery eyes
  - nasal and sinus congestion
  - runny nose
  - cough due to minor throat and bronchial irritation
  - itchy nose or throat
- temporarily reduces fever

**Warnings**

**Allergy alert:** Acetaminophen may cause severe skin reactions. symptoms may include:

- skin reddening
- blisters
- rash

**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**

- 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 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
- glaucoma
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- cough accompanied by excessive phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- 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 use more than directed (see overdose warning)**
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

**Stop use and ask a doctor if**

- redness or swelling is present
- 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
- 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:** 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 solution, propylene glycol, purified water, sodium benzoate, sodium citrate

### **Principal Display Panel**

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

Nighttime

Flu Relief Therapy

Severe Cold

Acetaminophen

Pain reliever; fever reducer

Diphenhydramine HCl

Cough suppressant; antihistamine

Phenylephrine HCl

Nasal decongestant

Relief of:

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

Alcohol Content: 10%

Cherry Flavor

For ages 12 & over

FL OZ (mL)

Questions or comments?

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

Distributed by AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

www.mygnp.com

**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., owner of the registered trademark Theraflu® Nighttime Severe Cold & Cough.

## Product Label

**GOOD NEIGHBOR PHARMACY**  
Compare to the active ingredients in Theraflu® Nighttime Severe Cold & Cough\*  
NDC 46122-311-33

**Nighttime Flu Relief Therapy** ALCOHOL 10%

**Severe Cold**

Pain Reliever/Fever Reducer (**Acetaminophen**)  
Cough Suppressant/Antihistamine (Diphenhydramine HCl)  
Nasal Decongestant (Phenylephrine HCl)

• Nasal Congestion • Sore Throat • Runny Nose  
• Headache • Body Ache • Cough • Fever

Cherry Flavor

Questions or comments?  
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Distributed By AmerisourceBergen  
1300 Morris Drive, Chesterbrook, PA 19087  
Questions or Concerns? Visit us at www.mygnp.com

8.3 fl oz (245 mL)

ABC# 10153414

0 8770142704 6  
PLD-02658 LB003435

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PLD-J265B  
LB003434

### Drug Facts

Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg.....	Pain reliever/fever reducer
Diphenhydramine HCl 25 mg.....	Antihistamine/ Cough suppressant
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
  - itching of the nose or throat
  - cough due to minor throat and bronchial irritation
  - temporarily reduces fever
- headache
- runny nose
- sneezing

PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

#### 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**

- to make a child sleepy
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- if you are now taking a prescription monoamine

### Drug Facts (continued)

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
- glaucoma
- high blood pressure
- heart disease
- diabetes
- thyroid disease
- 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, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks

PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

- 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

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- 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 rash or headache that lasts. These could be signs of a serious condition.

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Keep out of reach of children.

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### Drug Facts (continued)

#### Directions

- do not take more than directed (see overdose warning)
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- 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, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

Good Neighbor Pharmacy Nighttime Flu Relief Therapy

**NIGHTTIME FLU RELIEF THERAPY SEVERE COLD**

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46 122-311
<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: 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**

<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:46 122-311-33	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2015	12/31/2020

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/31/2015	12/31/2020

**Labeler** - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

Revised: 12/2018

AmerisourceBergen (Good Neighbor Pharmacy) 46122