

**SEVERE COLD RELIEF PE - acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated**

**WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

*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 caplet)***

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

***Uses***

- temporarily relieves these symptoms of the common cold:
- runny nose
- sneezing
- headache
- minor aches and pains
- nasal congestion
- cough
- sore throat
- temporarily reduces fever

***Warnings***

**Liver warning:**

This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than 12 caplets in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taking with other drugs containing acetaminophen
- adult has 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 whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- 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 an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if the user has**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- a cough accompanied by too much phlegm (mucus)
- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis

**Ask a doctor or pharmacist before use if the user is**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

**When using this product**

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

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, cough or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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. In

case of overdose, get medical help or contact a Poison Control Center 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 use more than directed (see overdose warning)

adults and children 12 years and over	take 2 caplets every 4 hours do not take more than 12 caplets in 24 hours
children 6 to under 12 years of age	take one caplet every 4 hours do not take more than 5 caplets in 24 hours
children under 6 years of age	do not use this product in children under 6 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

**Other information**

- see end flap for expiration date and lot number
- store at controlled room temperature 15°-30°C (59°-86°F)

**Inactive ingredients**

corn starch, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, stearic acid, talc, titanium dioxide

**Questions or comments?**

**1-800-426-9391**

**PRODUCT PACKAGING**

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

**CVS®**

**pharmacy**

Compare to the active ingredients in

Sudafed PE® Severe Cold\*

**See New Warnings Information**

**SEVERE**

**COLD RELIEF PE**

**MULTI-SYMP TOM**

**ACETAMINOPHEN,  
DIPHENHYDRAMINE HCl, PHENYLEPHRINE HCl  
PAIN RELIEVER/FEVER REDUCER, ANTIHISTAMINE  
COUGH SUPPRESSANT, NASAL DECONGESTANT**

- **Nasal & Sinus Congestion**
- **Fever & Body Aches**
- **Cough & Sore Throat**

**Does not contain Pseudoephedrine**

**24 COATED CAPLETS**

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS  
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

50844      REV1209B52608

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TAMPER EVIDENT: DO NOT USE IF CARTON IS  
OPENED OR IF BLISTER UNIT IS TORN, BROKEN  
OR SHOWS ANY SIGNS OF TAMPERING

Sudafed PE® Severe Cold®  
Compare to the active ingredients in  
**See New Warnings Information**

**CVS pharmacy**

**SEVERE COLD RELIEF PE  
MULTI-SYMPTOM**

**Does not contain Pseudoephedrine**

**24 COATED CAPLETS**

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**Drug Facts (continued)**

**Warnings:** This product contains acetaminophen. Severe liver damage may occur if:

- you take more than 12 caplets in 24 hours, which is the maximum daily amount.
- you take other drugs containing acetaminophen.
- you take with other drugs containing acetaminophen.
- you have a chronic liver condition.
- you have a history of alcohol abuse.
- you have a history of taking more than 2 grams of acetaminophen per day for 7 days or more.
- you have a history of taking more than 4 grams of acetaminophen per day for 14 days or more.
- you have a history of taking more than 6 grams of acetaminophen per day for 30 days or more.
- you have a history of taking more than 8 grams of acetaminophen per day for 60 days or more.
- you have a history of taking more than 10 grams of acetaminophen per day for 90 days or more.
- you have a history of taking more than 12 grams of acetaminophen per day for 120 days or more.
- you have a history of taking more than 14 grams of acetaminophen per day for 150 days or more.
- you have a history of taking more than 16 grams of acetaminophen per day for 180 days or more.
- you have a history of taking more than 18 grams of acetaminophen per day for 210 days or more.
- you have a history of taking more than 20 grams of acetaminophen per day for 240 days or more.
- you have a history of taking more than 22 grams of acetaminophen per day for 270 days or more.
- you have a history of taking more than 24 grams of acetaminophen per day for 300 days or more.
- you have a history of taking more than 26 grams of acetaminophen per day for 330 days or more.
- you have a history of taking more than 28 grams of acetaminophen per day for 360 days or more.
- you have a history of taking more than 30 grams of acetaminophen per day for 390 days or more.
- you have a history of taking more than 32 grams of acetaminophen per day for 420 days or more.
- you have a history of taking more than 34 grams of acetaminophen per day for 450 days or more.
- you have a history of taking more than 36 grams of acetaminophen per day for 480 days or more.
- you have a history of taking more than 38 grams of acetaminophen per day for 510 days or more.
- you have a history of taking more than 40 grams of acetaminophen per day for 540 days or more.
- you have a history of taking more than 42 grams of acetaminophen per day for 570 days or more.
- you have a history of taking more than 44 grams of acetaminophen per day for 600 days or more.
- you have a history of taking more than 46 grams of acetaminophen per day for 630 days or more.
- you have a history of taking more than 48 grams of acetaminophen per day for 660 days or more.
- you have a history of taking more than 50 grams of acetaminophen per day for 690 days or more.
- you have a history of taking more than 52 grams of acetaminophen per day for 720 days or more.
- you have a history of taking more than 54 grams of acetaminophen per day for 750 days or more.
- you have a history of taking more than 56 grams of acetaminophen per day for 780 days or more.
- you have a history of taking more than 58 grams of acetaminophen per day for 810 days or more.
- you have a history of taking more than 60 grams of acetaminophen per day for 840 days or more.
- you have a history of taking more than 62 grams of acetaminophen per day for 870 days or more.
- you have a history of taking more than 64 grams of acetaminophen per day for 900 days or more.
- you have a history of taking more than 66 grams of acetaminophen per day for 930 days or more.
- you have a history of taking more than 68 grams of acetaminophen per day for 960 days or more.
- you have a history of taking more than 70 grams of acetaminophen per day for 990 days or more.
- you have a history of taking more than 72 grams of acetaminophen per day for 1020 days or more.
- you have a history of taking more than 74 grams of acetaminophen per day for 1050 days or more.
- you have a history of taking more than 76 grams of acetaminophen per day for 1080 days or more.
- you have a history of taking more than 78 grams of acetaminophen per day for 1110 days or more.
- you have a history of taking more than 80 grams of acetaminophen per day for 1140 days or more.
- you have a history of taking more than 82 grams of acetaminophen per day for 1170 days or more.
- you have a history of taking more than 84 grams of acetaminophen per day for 1200 days or more.
- you have a history of taking more than 86 grams of acetaminophen per day for 1230 days or more.
- you have a history of taking more than 88 grams of acetaminophen per day for 1260 days or more.
- you have a history of taking more than 90 grams of acetaminophen per day for 1290 days or more.
- you have a history of taking more than 92 grams of acetaminophen per day for 1320 days or more.
- you have a history of taking more than 94 grams of acetaminophen per day for 1350 days or more.
- you have a history of taking more than 96 grams of acetaminophen per day for 1380 days or more.
- you have a history of taking more than 98 grams of acetaminophen per day for 1410 days or more.
- you have a history of taking more than 100 grams of acetaminophen per day for 1440 days or more.

**Do not use:**

- if you are taking other drugs containing acetaminophen (prescription or over-the-counter).
- if you are not sure 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.
- if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have:**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough accompanied by too much phlegm (mucus)

**Drug Facts (continued)**

**Directions:** Do not use more than directed (see overdose warning).

Children 12 years and over: Take one caplet every 4 hours. Do not take more than 12 caplets in 24 hours.

Children 6 to 12 years of age: Take one caplet every 4 hours. Do not take more than 5 caplets in 24 hours.

**Other information:** See and tag for expiration date and number store at controlled room temperature 15-30°C (59-86°F).

**Drug Facts (continued)**

**Warnings:** This product contains acetaminophen. Severe liver damage may occur if:

- you take more than 12 caplets in 24 hours, which is the maximum daily amount.
- you take other drugs containing acetaminophen.
- you take with other drugs containing acetaminophen.
- you have a chronic liver condition.
- you have a history of alcohol abuse.
- you have a history of taking more than 2 grams of acetaminophen per day for 7 days or more.
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- if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
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- if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have:**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough accompanied by too much phlegm (mucus)

**Drug Facts (continued)**

**Directions:** Do not use more than directed (see overdose warning).

Children 12 years and over: Take one caplet every 4 hours. Do not take more than 12 caplets in 24 hours.

Children 6 to 12 years of age: Take one caplet every 4 hours. Do not take more than 5 caplets in 24 hours.

**Other information:** See and tag for expiration date and number store at controlled room temperature 15-30°C (59-86°F).

B-0231-526-08  
REV1209B52608

**No Print Area**  
Lot no. & Expiration Date

SEVERE COLD RELIEF PE			
acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-526
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)		Acetaminophen	325 mg
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)		Diphenhydramine Hydrochloride	12.5 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)		Phenylephrine Hydrochloride	5 mg
Inactive Ingredients			
Ingredient Name			Strength
Starch, Corn (UNII: O8232NY3SJ)			

<b>Croscarmellose Sodium</b> (UNII: M28OL1HH48)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Cellulose, Microcrystalline</b> (UNII: OP1R32D61U)	
<b>Polyethylene Glycol</b> (UNII: 3WJQ0SDW1A)	
<b>Polyvinyl Alcohol</b> (UNII: 532B59J990)	
<b>Povidone</b> (UNII: FZ989GH94E)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	44;526
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-526-02	1 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:59779-526-08	1 in 1 CARTON		
2		24 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/21/2005	

**Labeler** - WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

**Registrant** - L.N.K. International, Inc. (832867837)

### Establishment

Name	Address	ID/FEI	Business Operations
L.N.K. International, Inc		832867894	MANUFACTURE