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.

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, condult 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 persistant 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 Centrer 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-SYMPTOM

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

Distributed by: **CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

www.cvs.com

1-800-shop-CVS

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)	

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

Product Characteristics

Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	44;526
Contains			

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

Revised: 8/2010 WOONSOCKET PRESCRIPTION CENTER, INCORPORATED