

**SINUS PE HEAD CONGESTION AND FLU SEVERE- acetaminophen,
dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

CVS 44-546-PPCH

Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 100 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves these symptoms due to the common cold:
 - headache
 - nasal congestion
 - cough
 - minor aches and pains
 - sore throat
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- 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:

- blisters
- rash
- skin reddening

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

- with any other drug containing acetaminophen (prescription or nonprescription). 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

- diabetes
- liver disease
- heart disease
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, 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
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **each caplet contains:** sodium 3 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

♥CVS™

NDC 51316-546-08

**SINUS PE HEAD CONGESTION
+ FLU SEVERE**

Acetaminophen, Pain Reliever, Fever Reducer
Dextromethorphan HBr, Cough Suppressant
Guaifenesin, Expectorant
Phenylephrine HCl, Nasal Decongestant

Compare to Sudafed PE® Head Congestion + Flu Severe active ingredients*

CAPLETS

Relieves: Sinus pressure,
Headache, Sore throat,
Cough, Chest congestion

actual
size

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

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Sudafed PE[®] Head Congestion + Flu Severe.

50844 ORG072254608

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no print / no varnish area
lot no. & exp. date

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

#970316
FPD 80%
UPC# 050428055403
XXXXXXXXXXXX X

Drug Facts (continued)
Other information ■ each caplet contains: sodium 3 mg
■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGING IS OPENED OR
■ BUSTER IS TORN OR BROKEN
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ see end flap for expiration date and lot number

Drug Facts (continued)
Inactive ingredients ■ corn starch, croscopolone, FD&C yellow #6
aluminum lake, magnesium stearate, malto-dextrin, microcrystalline cellulose,
polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch
glycolate, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-426-9391

Drug Facts (continued)
Warnings ■ temporarily reduces fever
■ 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: ■ rash ■ skin redness
If 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
■ with any other drug containing acetaminophen (prescription or
nonprescription). If you are not sure whether a drug contains
acetaminophen, ask a doctor or pharmacist.
■ If you are not taking a prescription monoamine oxidase inhibitor (MAOI)
(certain drugs for depression, anxiety 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 ■ diabetes ■ liver disease
■ heart disease ■ thyroid disease ■ high blood pressure

Drug Facts (continued)
Directions
■ do not take more than directed
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■ take 2 caplets every 4 hours
■ do not take more than 10 caplets in 24 hours
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Drug Facts (continued)
Keep out of reach of children. In case of overdose, get medical help or
contact a Poison Control Center right away. Prompt medical attention is
critical for adults as well as for children even if you do not notice any signs or
symptoms.
If pregnant or breast-feeding, ask a health professional before use.
be signs of a serious condition.
■ cough comes back or occurs with rash or headache that lasts. These could
be signs of a serious condition.
■ redness or swelling is present ■ new symptoms occur
■ fever gets worse or lasts more than 3 days
■ pain, cough, or nasal congestion gets worse or lasts more than 7 days
■ nervousness, dizziness, or sleeplessness occur
Stop use and ask a doctor if
■ When using this product do not exceed recommended dosage.
■ difficulty in urination due to enlargement of the prostate gland
■ persistent or chronic cough such as occurs with smoking, asthma, chronic
bronchitis, 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.

Drug Facts
Active ingredients (in each caplet)
Acetaminophen 325 mg Pain reliever/fever reducer
Dextromethorphan HBr 10 mg Cough suppressant
Guaifenesin 100 mg Expectorant
Phenylephrine HCl 5 mg Nasal decongestant

Drug Facts (continued)
Uses ■ temporarily relieves these symptoms due to the common cold:
■ headache ■ nasal congestion ■ cough ■ minor aches and pains
■ sore throat ■ sinus congestion and pressure
■ loosens phlegm (mucus) and thin bronchial secretions to drain bronchial
tubes and make coughs more productive

Drug Facts (continued)
When using this product do not exceed recommended dosage.

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trademark Sudafed PE® Head Congestion + Flu Severe. 50844 ORG072254608

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B-0251-546-06-PP1
ORG072254603

NDC 51316-546-08



SINUS PE HEAD CONGESTION + FLU SEVERE

Acetaminophen, Pain Reliever, Fever Reducer
Dextromethorphan HBr, Cough Suppressant
Guaifenesin, Expectorant
Phenylephrine HCl, Nasal Decongestant

Compare to Sudafed PE® Head Congestion + Flu Severe active ingredients*

24
CAPLETS

Relieves: Sinus pressure,
Headache, Sore throat,
Cough, Chest congestion



CVS 44-546

SINUS PE HEAD CONGESTION AND FLU SEVERE
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-546
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	44;546
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-546-08	2 in 1 CARTON	09/25/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/25/2021	

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-546) , pack(51316-546)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-546)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-546)

Revised: 12/2025

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