

**NASAL DECONGESTANT PE AND PAIN RELIEF PLUS MUCUS RELIEF-  
acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated  
Winco Foods, LLC**

*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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**WNC - 1173 - 2019-1101**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
  - sinus congestion and pressure
  - headache
  - minor aches and pains
  - nasal congestion
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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.

### **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**

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

**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, nasal congestion, or cough 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.**

### **Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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)**

adults and children 12 years and over	<ul style="list-style-type: none"> <li>▪ take 2 caplets every 4 hours</li> <li>▪ do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>▪ ask a doctor</li> </ul>

### **Other information**

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, crospovidone, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

### **Questions?**

Call 800-824-1706 Monday - Friday 9am - 4pm MST

### **PRINCIPAL DISPLAY PANEL**

Winco FOODS

\*Compare to the active ingredients in SUDAFED PE(R) Pressure + Pain + Mucus

Non-Drowsy

Nasal Decongestant PE & Pain Relief

Plus Mucus Relief

Relieves: Sinus Pressure & Congestion, Sinus Headache, Chest Congestion

24 Caplets

ACETAMINOPHEN/

PAIN RELIEVER - FEVER REDUCER

PHENYLEPHRINE HCl / NASAL DECONGESTANT

GUAIFENESIN / EXPECTORANT

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<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b> Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3.250 mg acetaminophen) in 24 hours. 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 skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b> ■ 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</p> <p><b>Ask a doctor before use if you have</b> ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema</p> <p>■ cough that occurs with too much phlegm (mucus)</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> adults and children ■ take 2 caplets every 4 hours ■ do not take more than 10 caplets in 24 hours ■ ask a doctor</p> <p>children under 12 years</p> <p>▲</p>
<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b> Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p> <p><b>Stop use and ask a doctor if</b> ■ nervousness, dizziness, or sleeplessness occur ■ pain, nasal congestion, or cough 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.</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> adults and children ■ take 2 caplets every 4 hours ■ do not take more than 10 caplets in 24 hours ■ ask a doctor</p> <p>children under 12 years</p> <p>▲</p>

<p><b>Drug Facts (continued)</b></p> <p><b>Active ingredients (in each caplet)</b> Acetaminophen 325 mg.....Pain reliever/fever reducer Guaifenesin 200 mg.....Expectorant Phenylephrine HCl 5 mg.....Nasal decongestant</p> <p><b>Uses</b> ■ temporarily relieves these symptoms associated with passages of bothersome mucus and make coughs more productive ■ temporarily reduces fever</p>	<p><b>Drug Facts (continued)</b></p> <p>may fever or other upper respiratory allergies, and the common cold: ■ sinus congestion and pressure ■ headache ■ nasal congestion ■ minor aches and pains ■ helps loosen phlegm (mucus) and thin bronchial secretions to the bronchial passages of bothersome mucus and make coughs more productive</p>
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# Nasal Decongestant PE & Pain Relief

## Plus Mucus Relief

Compare to the active ingredients in SUDAFED PE® Pressure + Pain + Mucus

Non-Drowsy  
.....  
Relieves: Sinus Pressure & Congestion, Sinus Headache, Chest Congestion  
.....



**24**  
Caplets

**ACETAMINOPHEN/  
PAIN RELIEVER - FEVER REDUCER  
PHENYLEPHRINE HCl / NASAL DECONGESTANT  
GUAIFENESIN / EXPECTORANT**

**DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704**  
 \* This product is not manufactured or distributed by MCNEIL CONSUMER HEALTHCARE, distributor of SUDAFED PE® Pressure + Pain + Mucus.  
**100% SATISFACTION GUARANTEE**  
 Comments & Questions: 800-824-1706  
**DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN**

<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b> ■ store between 20-25°C (68-77°F) in a dry place ■ retain carton for complete product information</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients</b> croscarmellose sodium, crospovidone, magnesium stearate, colloidal silicon dioxide</p>
<p><b>Drug Facts (continued)</b></p> <p>maltoedextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide</p>	<p><b>Questions?</b> Call 800-824-1706 Monday - Friday 9am - 4pm MST</p>

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# NASAL DECONGESTANT PE AND PAIN RELIEF PLUS MUCUS RELIEF

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67091-349
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<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>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	AAA;1173
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-349-24	2 in 1 CARTON	10/25/2017	
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 final	part341	10/25/2017	

**Labeler** - Winco Foods, LLC (056098817)

Revised: 12/2022

Winco Foods, LLC