#### NASAL DECONGESTANT PE AND PAIN RELIEF MAXIMUM STRENGTHacetaminophen, phenylephrine hcl tablet WinCo Foods, LLC

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Winco 44-502

#### Active ingredients (in each caplet)

Acetaminophen 325 mg Phenylephrine HCl 5 mg

#### **Purpose**

Pain reliever/fever reducer Nasal decongestant

#### Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
  - minor aches and pains
  - nasal congestion
  - headache
  - sinus congestion and pressure
- promotes sinus drainage
- 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:

- 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

- diabetes
- liver disease
- heart disease
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

#### 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 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

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 accidental 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 use 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

#### 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, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide, stearic acid

#### **Questions?**

Call 1-800-824-1706 Monday - Friday 9am - 4pm MST

#### **Principal Display Panel**

**WinCo**® FOODS

**MAXIMUM STRENGTH** 

Nasal
Decongestant PE
& Pain Relief

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

Non-Drowsy

Relives: Sinus Headache, Sinus Pressure & Nasal Congestion

#### ACETAMINOPHEN/

PAIN RELIEVER - FEVER REDUCER
PHENYLEPHRINE HCI/NASAL DECONGESTANT

#### 24

Caplets

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

**DISTRIBUTED BY:** WINCO FOODS, LLC, BOISE, ID 83704

\*This product is not manufactured or distributed by JOHNSON & JOHNSON CORPORATION,

distributor of SUDAFED PE® Pressure + Pain.

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#### **100% SATISFACTION GUARANTEE**

Comments & Questions? 800-824-1706

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

No print/No varnish Lot & Exp date

Ask a dodor or pharmacist before use if you are taking the blood trinning

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- Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms ■ 3 or more alcoholic drinks every day while using this product
  - with other drugs containing acetaminophen may occur if you take more than 4,000 mg of acetaminophen in 24 hours
- Liver warning: This product contains acetaminophen. Severe liver damage

Warnings

Drug Facts (confined)

Drug Facts

\*Compare to the active ingredients in

SUDAFED PE® Sinus Pressure + Pain

Non-Drowsy

Relieves: Sinus Headache,

Sinus Pressure & Nasal Congestion

microcrystalline cellulose, povidone, silicon dioxide, stearic acid

- crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, Inactive ingredients corn starch, croscarmellose sodium,
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    - take 2 caplets every 4 hours
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- fever gets worse or lasts more than 3 days ■ pain 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.

Drug Facts (continued)

■ temporarily reduces fever ■ bromotes sinus drainage

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Purpose Active ingredients (in each caplet)

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Drug Facts (continued)

WinCo

MAXIMUM STRENGTH

Nasal **Decongestant PE** & Pain Relief

ACETAMINOPHEN/ PAIN RELIEVER - FEVER REDUCER PHENYLEPHRINE HCI/NASAL DECONGESTANT

Winco 44-502

B-2150-502-08

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100% SATISFACTION GUARANTEE
Comments & Questions? 800-824-1706

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

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REV0820C50208

# NASAL DECONGESTANT PE AND PAIN RELIEF MAXIMUM STRENGTH

acetaminophen, phenylephrine hcl tablet

Droduct	Inform	\ation
<b>Product</b>		ıatıvı

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-209

**Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
(	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	44;502
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:67091- 209-24	2 in 1 CARTON	06/23/2005		
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	06/23/2005		

# Labeler - WinCo Foods, LLC (056098817)

# EstablishmentNameAddressID/FEIBusiness OperationsLNK International, Inc.832867837manufacture(67091-209), pack(67091-209)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		117025878	manufacture(67091-209)	

Revised: 5/2023 WinCo Foods, LLC