# WAL-PHED PE PRESSURE PLUS PAIN MAXIMUM STRENGTH NON-DROWSYacetaminophen, phenylephrine hcl tablet Walgreen Company

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.

-----

Walgreens 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

- heart disease
- thyroid disease
- diabetes
- liver 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 (1-800-222-1222) 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 or comments?

1-800-426-9391

## **Principal Display Panel**

#### Walgreens

Compare to Sudafed  $PE^{\circledR}$  Pressure + Pain active ingredients  $^{\dagger\dagger}$ 

NDC 0363-5020-08

**NON-DROWSY** 

Wal-Phed® PE

PRESSURE + PAIN

**ACETAMINOPHEN** 325 mg / PAIN RELIEVER / FEVER REDUCER PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

**MAXIMUM STRENGTH** 

#### • Relieves:

Sinus headache, sinus pressure, nasal congestion

• Pseudoephedrine free

**24** CAPLETS

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

#### **DOES NOT CONTAIN GLUTEN**

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

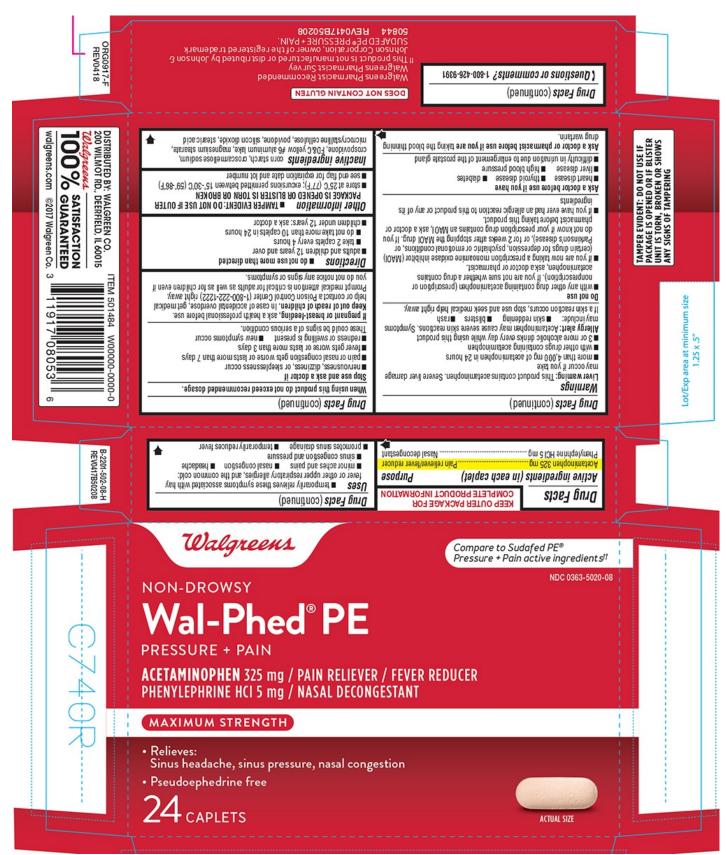
††This product is not manufactured or distributed by Johnson & Johnson corporation, owner of the registered trademark SUDAFED PE® PRESSURE + PAIN.

50844 REV0417B50208

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

Walgreens 100% SATISFACTION GUARANTEED

walgreens.com ©2017 Walgreen Co.



44-502

#### WAL-PHED PE PRESSURE PLUS PAIN MAXIMUM STRENGTH NON-DROWSY

acetaminophen, phenylephrine hcl tablet

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-5020
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)				
CROSPOVIDONE (UNII: 2S7830E561)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
PO VIDO NE (UNII: FZ989 GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				

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

]	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:0363-5020- 08	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 FINAL	part341	06/23/2005		

# Labeler - Walgreen Company (008965063)

Establishment				
Name	Address	ID/FEI	Business Operations	

LNK International, Inc.	832867894	MANUFACTURE(0363-5020)	
-------------------------	-----------	------------------------	--

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	PACK(0363-5020)	

Revised: 3/2020 Walgreen Company