PRESSURE PLUS PAIN PLUS MUCUS NON-DROWSY- acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated 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 44-527C-PPM

Active ingredients (in each caplet)

Acetaminophen 325 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Expectorant Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
 - sinus congestion and pressure
 - minor aches and pains
 - nasal congestion
 - headache
- helps loosen phlegm (mucus) and thin bronchial secretions to 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.

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
- heart disease
- thyroid disease
- liver disease
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- difficulty in urination due to enlargement of the prostate gland
- 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

- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- nervousness, dizziness, or sleeplessness occur
- 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 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 take more than directed
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - swallow whole do not crush, chew, or dissolve
 - 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, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

Walgreens

Compare to SUDAFED PE[®] Pressure + Pain + Mucus active ingredients^{‡‡}

NDC 0363-4120-08

NON-DROWSY

Wal-Phed[®] PE

PRESSURE + PAIN + MUCUS

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

MULTY-SYMPTOM

• Relieves sinus pressure/congestion, sinus headache & chest congestion

Pseudoephedrine free

24 CAPLETS Actual Size

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

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 + Mucus.

50844 ORG091752708

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Walgreens 44-527C

PRESSURE PLUS PAIN PLUS MUCUS NON-DROWSY

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

Product Informat	tion							
Product Type		HUMAN OTC D	DRUG I	tem Code	m Code (Source) NDC:		C:0363-4120	
Route of Administra	tion	ORAL						
itoute of / fulling tu	uon							
Active Ingredient	/Active	Moiety						
		Ingredient Name			Basis of S	Strength	Strengt	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOP						HEN 325 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN							200 mg	
PHENYLEPHRINE HYDRO CHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - PHENYLEPHRINE							5 mg	
UNII:1WS297W6MV) HYDROCHLORIDE						DE	Jing	
Inactive Ingredie	nts							
0		Ingred	lient Name				Strength	
STARCH, CORN (UNII: 08232NY3SJ)								
CROSPOVIDONE (UN								
MAGNESIUM STEARA								
MALTO DEXTRIN (UN								
MICROCRYSTALLIN			61U)					
POLYETHYLENE GLY								
POVIDONE (UNII: FZ9			52002(11)					
SILICON DIO XIDE (U								
STEARIC ACID (UNII:								
SUCRALOSE (UNII: 96								
TALC (UNII: 7SEV7J4F)						
TITANIUM DIO XIDE (X9 V2JP)						
SODIUM STARCH GL			UNII: 5856J3G2A2)				
POLYVINYL ALCOH				, 				
		X	,					
Product Characte	ristics							
Color	WHITE Score			no score				
Shape		OVAL	Size			19 mm		
Flavor			Imprint Code			44;527		
Contains								
Packaging								
# Item Code		Package Desc	cription	M	arketing Start Da	te Marketi	ng End Dat	
1 NDC:0363-4120-08	2 in 1 CAF	RTON			/06/2005			
1	12 in 1 BL	ISTER PACK; Type 0: I	Not a Combination	Product				
Marketing Info	ormati	ion						
Marketing Catego	ry Ap	plication Number o	r Monograph Ci	tation M	arketing Start Dat	e Marketi	ng End Dat	

Labeler - Walgreen Company (008965063)

Establishment									
Name	Address	ID/FEI	Business Operations						
LNK International, Inc.		832867894	MANUFACTURE(0363-4120)						
Establishment									
Name	Address	ID/FEI	Business Operations						
LNK International, Inc.		832867837	PACK(0363-4120)						

Revised: 5/2020

Walgreen Company