

PRESSURE AND PAIN PE PLUS MUCUS- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
Supervalu Inc.

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.

ELN - 1173 - 2015-0326

Drug Facts

Active ingredients (in each caplet)	Purpose
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

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	▪ 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

- 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

PRINCIPAL DISPLAY PANEL

Equaline®

NDC 41163-512-02

compare to Sudafed PE® Pressure+Pain+Mucus active ingredients†

pressure & pain PE

plus mucus

non-drowsy, for adults

acetaminophen (pain reliever/fever reducer)

phenylephrine HCl (nasal decongestant)

guaifenesin (expectorant)

relieves: sinus headache

sinus pressure & congestion

chest congestion

24 caplets

PRESSURE AND PAIN PE PLUS MUCUS

Drug Facts (continued)

■ 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 (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 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 ■ thyroid disease ■ diabetes ■ high blood pressure ■ 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)

Drug Facts (continued)

Directions

■ do not take more than directed (see overdose warning)

adults and children 12 years and over ■ take 2 caplets every 4 hours ■ do not take more than 10 caplets in 24 hours ■ ask a doctor if children under 12 years

Drug Facts (continued)

When using this product do not exceed recommended dosage

■ blood thinning drug warfarin

Stop use and ask a doctor if

■ pain, nasal congestion, or cough gets worse or lasts more than 7 days

■ fever gets worse or lasts more than 3 days

■ 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.

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Guafenesin 200 mg.....Expectorant

Phenylephrine HCl 5 mg.....Nasal decongestant

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Drug Facts (continued)

■ hay 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 rid the bronchial passageways of bothersome mucus and make coughs more productive

compare to Sudafed PE®

Pressure + Pain + Mucus

active ingredients†

EQUALINE®

pressure & pain PE plus mucus

non-drowsy, for adults

acetaminophen (pain reliever/fever reducer)

phenylephrine HCl (nasal decongestant)

guaifenesin (expectorant)

relieves:

- sinus headache
- sinus pressure & congestion
- chest congestion

24 caplets

actual size

DISTRIBUTED BY SUPervalu INC.
EDEN PRAIRIE, MN 55344 USA
Contact us at 1-877-932-7948, or
www.supervalu-ourwinbrands.com

F117302ELN_R0

†This product is not manufactured or distributed by McKel-Corcoran Healthcare, distributor of Sudafed PE® Pressure + Pain + Mucus.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

Drug Facts (continued)

Other information

■ store between 20-25°C (68-77°F) in a dry place

■ retain carton for complete product information

Drug Facts (continued)

Inactive ingredients

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



acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-512	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
CROSPVIDONE (UNII: 68401960MK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	AAA;1173	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-512-02	2 in 1 CARTON	08/01/2014	12/31/2024
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	08/01/2014	12/31/2024

Labeler - Supervalu Inc. (006961411)

Revised: 9/2022

Supervalu Inc.