# PRESSURE PAIN AND COLD SUPHEDRINE PE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated DISCOUNT DRUG MART

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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#### 1174-DDM-2021-1127

#### **Drug Facts**

Active ingredients (in each caplet)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- temporarily relieves these symptoms due to the common cold:
  - nasal congestion
  - headache
  - minor aches and pains
  - cough
  - sore throat
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes 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

#### Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### 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> <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	■ 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, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

#### PRINCIPAL DISPLAY PANEL

DISCOUNT drug mart FOOD FAIR

†Compare to the Active Ingredients in Sudafed PE® Pressure + Pain + Cold

PRESSURE+PAIN+COLD

SUPHEDRINE PE

For Adults

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

Pain Reliever/Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

#### Relieves:

- Sinus Headache & Sore Throat
- Sinus Pressure & Congestion
- Cough
- Chest Congestion

**NON - DROWSY** 

24 CAPLETS

- asthma, chronic bronchitis, or emphysema becaragent or chronic cough such as occurs with smoking,
  - trouble urinating due to an enlarged prostate gland
    - diabetes
- µidµ plood pressure в реац disease ■ Ask a doctor before use if you have ■ liver disease

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- it you have ever had an allergic reaction to this product or any an MAOI, ask a doctor or pharmacist before taking this product. the MAOI drug. If you do not know if your prescription drug contains conditions, or Parkinson's disease), or for 2 weeks after stopping (MAOI) (certain drugs for depression, psychiatric, or emotional it you are now taking a prescription monoamine oxidase inhibitor scetaminophen, ask a doctor or pharmacist.
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Drug Facts (continued)

Drug Facts

F117402DDM R0

Distributed by: Drug Mart - Food Fair 211 Commerce Drive Medina, OH 44256

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Pressure + Pain + Cold.

USE IF BLISTER UNITS TORN OR BROKEN

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•	■ ssk s doctor	children under 12 years
	■ take 2 caplets every 4 hours ■ take 2 caplets in 24 hours	adults and children 12 years and over

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If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition.

- cough comes back or occurs with rash or headache that lasts uew symptoms occur tedness of swelling is present ■ fever gets worse or lasts more than 3 days than 7 days
  - pain, nasal congestion, or cough gets worse or lasts more ■ uervousness, dizziness, or sleeplessness occur

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Drug Facts (continued)

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Vasal decongestant Рћепујерћгіпе НСІ 5 тд Expectorant Guaifenesin 100 mg. Cough suppressant Dextromethorphan HBr 10 mg. Purpose Active ingredients (in each caplet)

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nund racts (confined)

†Compare to the Active Ingredients in Sudafed PE® Pressure + Pain + Cold

PRESSURE + PAIN + COLD



# SUPHEDRINE PE For Adults

Acetaminophen, Phenylephrine HCI, Dextromethorphan HBr, Guaifenesin Pain Reliever/Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

- Sinus Headache & Sore Throat
- Sinus Pressure & Congestion
- Cough

24 CAPLETS



- Chest Congestion

- croscarmellose sodium, crospovidone, FD&C yellow #6 Inactive ingredients colloidal silicon dioxide,
  - retain carton for complete product information Other information

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

Drug Facts (continued)

**NON - DROWSY** 

aluminum lake, magnesium stearate, maltodextrin, microcrystalline

cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

nund racts (continued)

## PRESSURE PAIN AND COLD SUPHEDRINE PE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-174
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;1134
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:53943- 174-02	2 in 1 CARTON	05/16/2014	06/30/2024

	2 in 1 BLISTER PACK; Type 0: Not a Combination roduct			
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	05/16/2014	06/30/2024	

## Labeler - DISCOUNT DRUG MART (047741335)

Revised: 9/2022 DISCOUNT DRUG MART