HEAD CONGESTION PLUS FLU SEVERE 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.

1174-DDM-2022-1123

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
 - sinus congestion and pressure
- 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

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.

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	 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 and warnings

Inactive ingredients

colloidal silicon dioxide, corn starch, 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

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

DISCOUNT drug mart FOOD MARKET

NDC 53843-274-02

†Compare to the active ingredients in Sudafed PE® Head Congestion + Flu Severe HEAD CONGESTION + FLU SEVERE PE

Acetaminophen. Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl

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

For Relief OF

- Sinus Pressure Heachache Cough
- Sore Throar Chest Congestion

Actual Size

8

NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Head Congestion + Flu Severe.

211 Commerce Drive

Distributed

d by: Drug Mart - For

Mart - Food Fair Medina, OH 44256

com starch, croscarmellose sodium, crospovidone, Questions or comments? #854-507-##8-F Inactive ingredients coloidal silicon dioxide, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide ■ retain carton for complete product information and warnings microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, ■ store between 20-25°C (68-77°F) in a dry place Other information FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, Drug Facts (continued) Drug Facts (continued) 12 years diabetes thyroid disease SSK S GOCTOF children under pigh blood pressure ■ heart disease ■ liver disease Ask a doctor before use if you have ■ do not take more than 10 caplets in 24 hours IS Years and over of its ingredients ■ take 2 caplets every 4 hours adults and children if you have ever had an allergic reaction to this product or any Directions = do not take more than directed (see overdose warning) an MAOI, ask a doctor or pharmacist before taking this product. the MAOI drug. If you do not know if your prescription drug contains uonce sult sidus or symptoms. conditions, or Parkinson's disease), or for 2 weeks after stopping attention is critical for adults as well as for children even if you do not (MAOI) (certain drugs for depression, psycniatinc or emotional Poison Control Center right away (1-800-222-1222). Quick medical it you are now taking a prescription monoamine oxidase inhibitor Over dose warning: In case of overdose, get medical help or contact a acetaminophen, ask a doctor or pharmacist. Keep out of reach of children. nonprescription). If you are not sure whether a drug contains If pregnant or breast-feeding, ask a health professional before use. ■ with any other drug containing acetaminophen (prescription or These could be signs of a serious condition. cough comes back or occurs with rash or headache that lasts vomiting, consult a doctor promptly. uew symptoms occur ■ redness or swelling is present days, is accompanied or followed by fever, headache, rash, nausea, or ■ fever gets worse or lasts more than 3 days Sore throat warning: It sore throat is severe, persists for more than 2 ■ bain, nasal congestion, or cough gets worse or lasts more than 7 days If a skin reaction occurs, stop use and seek medical help right away. ■ nervousness, dizziness, or sleeplessness occur Allergy alert. Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash Stop use and ask a doctor if Mhen using this product do not exceed recommended dosage 3 or more alcoholic drinks every day while using this product thinning drug wartarin ■ with other drugs containing acetaminophen Ask a doctor or pharmacist before use if you are taking the blood ■ more than 4,000 mg of acetaminophen in 24 hours Severe liver damage may occur if you take F117402DDM condp that occurs with too much philegm (mucus) 0 dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. sathma, chronic bronchitis, or empnysema Liver warming: This product contains acetaminophen. The maximum daily becase of chronic conditions as occurs with smoking, Warnings ■ trouble uninating due to an enlarged prostate gland **Drug Facts** (continued) Drug Facts (confined)

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Рһепуlерһппе НСІ 5 тд wasai decongesant Expectorant Guaifenesin 100 mg Cough suppressant Dextromethorphan HBr 10 mg. Active ingredients (in each caplet) Purpose Drug Facts

NDC 53943-274-02

†Compare to the active ingredients in Sudafed PE® Head Congestion + Flu Severe

HEAD CONGESTION + FLU SEVERE PE

Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl

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

Sinus Pressure

- Cough

For Relief Of

- Sore Throat
- Headache

Chest Congestion

24 CAPLETS

HEAD CONGESTION PLUS FLU SEVERE PE

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

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-274	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)			
STARCH, PREGELATINIZED 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

1 NDC:53943- 274-02	2 in 1 CARTON	08/01/2022	
1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category					
OTC monograph final	part341	08/01/2022			

Labeler - DISCOUNT DRUG MART (047741335)

Revised: 11/2022 DISCOUNT DRUG MART