# HEAD CONGESTION FLU SEVERE PE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated GOODSENSE

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-GDS-2022-0804

#### **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	<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 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

#### PRINCIPAL DISPLAY PANEL

**GOODSENSE®** 

NDC 50804-274-02

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
- Headache
- Sore Throat
- Cough
- Chest Congestion

24 CAPLETS

**Actual Size** 

#### Compare to active ingredients of Sudafed PE® Head Congestion + Flu Severet

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Drug Facts (continued)

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Drug Facts (continued)

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NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

s product is not manufactured or ributed by McNeil Consumer thcare, distributor of Sudated PE® d Congestion + Flu Severe.

Distributed by:
Perrigo Direct, Inc.
Peachtree City, GA 30269
www.PerrigoDirect.com
1-844-705-4384
GoodSense® is a registered
trademark of L. Perrigo Company.

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Drug Facts

GOODSENSE.

NDC 50804-274-02

# **Head Congestion**

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

For Relief of

- Sinus Pressure
- Sore Throat

Chest Congestion

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

Cough

Headache

24 CAPLETS

# **HEAD CONGESTION FLU SEVERE PE**

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-274

**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: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (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: 4ELV7Z 65AP)	
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			
# Hom Code	Daalaaa Daaarintian	Marketing Start	Marketing End

#	item code	Раскаде резсприон	Date	Date
1	NDC:50804- 274-02	2 in 1 CARTON	08/03/2022	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
• • • • • • • • • • • • • • • • • • • •	larketing End Date		
al part341 08/03/2022			
2.00	Da		

# Labeler - GOODSENSE (076059836)

Revised: 8/2022 GOODSENSE