HEAD CONGESTION PLUS FLU SEVERE PE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated MEIJER DISTRIBUTION 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.

1174-MEI-2022-0923

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

meijer®

NDC 41250-574-02

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

head congestion + flu severe PE

Acetaminophen | Dextromethorphan HBr | Guaifenesin | Phenylephrine HCl

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

Relief of: • Sinus Pressure • Headache

• Sore Throat • Cough • Chest Congestion

24 CAPLETS

actual size

com starch, croscarmellose sodium, crospovidone, 1-844-705-4384 Unestions or comments? Inactive ingredients colloidal silicon dioxide, ■ store between 20-25°C (68-77°F) in a dry place retain carton for complete product information and warnings povidone, pregelatinized starch, stearic acid, talc, titanium dioxide microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, Other information **Drug Facts** (continued) Drug Facts (continued) uiðu pjoog blessnie children under aspasid tibali = aspasio janii ... Ask a doctor before use if you have ■ qo uot take more than 10 caplets in 24 hours 12 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 DIFECTIONS • 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 notice any signs or symptoms. conditions, or Parkinson's disease), or 10r'2 weeks after stopping (MAOI) (certain drugs for depression, psychiatric or emotional It you are now taking a prescription monoamine oxidase inhibitor

Keep out of reach of children.

- condh comes back or occurs with rash or headache that lasts ■ redness or swelling is present
- baju' uasal congestion, or cough gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleeplessness occur

When using this product do not exceed recommended dosage

Ask a doctor or pharmacist before use if you are taking the blood condy tyst occnts with too much bylegm (mucus)

Drug Facts (continued)

attention is critical for adults as well as for children even if you do not Poison Control Center right away (1-800-222-1222). Quick medical Overdose warning: In case of overdose, get medical help or contact a

If pregnant or breast-feeding, ask a health professional before use.

These could be signs of a serious condition.

 uew symptoms occur ■ Tever gets worse or lasts more than 3 days

Stop use and ask a doctor if

thinning drug warfarin

■ helps loosen phlegm (mucus) and thin bronchial secretions to

USes a temporarily relieves these symptoms due to the

sathma, chronic bronchitis, or emphysema bersistent or chronic cough such as occurs with smoking, ■ trouble uninating due to an enlarged prostate gland

sinus congestion and pressure

■ minor aches and pains ■ cough

common cold:

■ nasal congestion

acetaminophen, ask a doctor or pharmacist. nonprescription). If you are not sure whether a drug contains PID 3534002

■ with any other drug containing acetaminophen (prescription or oo not use vomiting, consult a doctor promptly.

days, is accompanied or followed by fever, headache, rash, nausea, or Sore throat warning: If sore throat is severe, persists for more than 2 if a skin reaction occurs, stop use and seek medical help right away. Symptoms may include: ■ skin reddening ■ blisters ■ rash Allergy alert: Acetaminophen may cause severe skin reactions.

 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen

■ more than 4,000 mg of acetaminophen in 24 hours Severe liver damage may occur if you take

dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Liver warning: This product contains acetaminophen. The maximum daily Warnings

Drug Facts (continued)

 femboranily reduces tever drain bronchial tubes and make coughs more productive

Nasal decongestant Рћепујерћипе НСІ 5 тд. Guaifenesin 100 mg. Expectorant Cough suppressant Dextromethorphan HBr 10 mg.

Active ingredients (in each caplet) Drug Facts

Drug Facts (continued)

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

meijer

■ sore unroat

head congestion + flu severe PE

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

> elief of: • Sinus Pressure • Headache • Sore Throat • Cough • Chest Congestion

> > 24 CAPLETS



This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Sudafed PE®.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

F117402MEI_R2

2

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:41250-574

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 (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 |

| 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | | NDC:41250- 574-02 | 2 in 1 CARTON | 09/23/2022 | |
|---|---|----------------------|---------------|------------|--|
| | 1 | | | | |

| Marketing Information | | | |
|---|---|---|--|
| Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| part341 | 09/23/2022 | | |
| | Application Number or Monograph Citation | Application Number or Monograph Marketing Start Citation Date | |

Labeler - MEIJER DISTRIBUTION INC (006959555)

Revised: 9/2022 MEIJER DISTRIBUTION INC