ALLERGY MULTI-SYMPTOM- acetaminophen, chlorpheniramine maleate, 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.

GDS - 1128 - 2017-0921

Drug Facts

| Active ingredients (in each caplet) | Purpose | |
|-------------------------------------|--------------------|--|
| Acetaminophen 325 mg | Pain reliever | |
| 1 0 | PainTenever | |
| Chlorpheniramine maleate 2 | Antihistamin | |
| mg | Timinstanine | |
| Phenylephrine HCl 5 mg | Nasal decongestant | |

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 - headache
 - sinus congestion and pressure
 - nasal congestion
 - runny nose and sneezing
 - minor aches and pains
- temporarily relieves these additional symptoms of hay fever:
 - itching of the nose or throat
 - itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus openings and passages

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- 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.

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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion 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

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)

- take 2 caplets every 4 hours
- swallow whole do not crush, chew,

| children 12 years and over | or dissolve ■ do not take more than 12 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

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, flavor, hypromellose, iron oxide ochre, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

GoodSense

NDC 50804-828-03

For Adults

Allergy Multi-Symptom

Pain Reliever/Acetaminophen

Antihistamine/Chlorpheniramine Maleate

Nasal Decongestant/Phenylephrine HCl

Cool Taste; Instant Cooling Sensation

Headache

Sinus Pressure

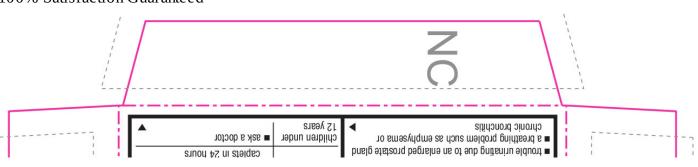
Nasal Congestion

Runny Nose/Sneezing

Itchy, Watery Eyes

24 Caplets

100% Satisfaction Guaranteed



- djancoma ■ diabetes
- thyroid disease high blood pressure ■ heart disease ■ liver disease

Ask a doctor before use if you have

product or any of its ingredients

- if you have ever had an allergic reaction to this doctor or pharmacist before taking this product. your prescription drug contains an MAOI, ask a stopping the MAOI drug. If you do not know if or Parkinson's disease), or for 2 weeks after depression, psychiatric, or emotional conditions, oxidase inhibitor (MAN) (certain drugs for
- if you are now taking a prescription monoamine doctor or pharmacist. whether a drug contains acetaminophen, ask a
- (prescription or nonprescription). If you are not sure
 - with any other drug containing acetaminophen Do not use

help right away.

If a skin reaction occurs, stop use and seek medical

■ skin reddening
■ blisters reactions. Symptoms may include:

Allergy alert: acetaminophen may cause severe skin product

- 3 or more alcoholic drinks every day while using this ■ with other drugs containing acetaminophen
- maximum daily amount ■ more than 12 caplets in 24 hours, which is the Severe liver damage may occur if you take Liver warning: This product contains acetaminophen.

Marnings

■ itchy, watery eyes hay fever: a itching of the nose or throat ■ temporarily relieves these additional symptoms of

Drug Facts (continued)

■ do not take more than 12 chew, or dissolve years and over

swallow whole - do not crush, children 12 ■ take 2 caplets every 4 hours

adults and do not take more than directed (see overdose warning) Directions

notice any signs or symptoms. for adults as well as for children even if you do not [1-800-222-1222]. Quick medical attention is critical help or contact a Poison Control Center right away Overdose warning: In case of overdose, get medical Keep out of reach of children. professional before use.

If pregnant or breast-feeding, ask a health

These could be signs of a serious condition.

- new symptoms occur
- redness or swelling is present
- fever gets worse or lasts more than 3 days than 7 days
- pain or nasal congestion gets worse or lasts more
- nervousness, dizziness, or sleeplessness occur Stop use and ask a doctor if

operating machinery

- be careful when driving a motor vehicle or drowsiness
- alcohol, sedatives, and tranquilizers may increase
- drowsiness may occur avoid alcoholic drinks
 - excitability may occur, especially in children

■ do not exceed recommended dosage When using this product

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers
- Ask a doctor or pharmacist before use if you are

Drug Facts (continued)

 helps decongest sinus openings and passages ■ µejbe cjest usesj basesĝes

■ minor aches and pains ■ nasal congestion
■ runny nose and sneezing sinus congestion and pressure ■ рездасре

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Phenylephrine HCI 5 mg......Nasal decongestant Chlorpheniramine maleate 2 mg..... Antihistamine Acetaminophen 325 mg.

(in each caplet) Active ingredients Purpose

Drug Facts

hay fever or other upper respiratory allergies: temporarily relieves these symptoms of

Drug Facts (continued)

GOODSENSE.

NDC 50804-828-03

For Adults



Pain Reliever/Acetaminophen Antihistamine/ChlorpheniramineMaleate Nasal Decongestant/PhenylephrineHCl

- Headache
- Sinus Pressure
- Nasal Congestion



Distributed by: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269 www.valuelabels.com



O NOT USE IF BL

Questions or comments? 1-844-705-4384

Inactive ingredients acesultame potassium, colloidal silicon dioxide, croscarmellose sodium, flavor, hypromellose, iron oxide ochre, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

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

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

Drug Facts (continued)

ALLERGY MULTI-SYMPTOM

acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride tablet, coated

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:50804-828

Route of Administration ORAL

| Active Ingredient/Active Moiety | | |
|--|--------------------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) | ACETAMINOPHEN | 325 mg |
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 2 mg |
| PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| ACESULFAME POTASSIUM (UNII: 230 V73Q5G9) | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | | |
| HYPROMELLOSES (UNII: 3NXW29 V3WO) | | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| PO VIDONE (UNII: FZ989GH94E) | | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | | |

Product Characteristics

| Color | white (Off-White) | Score | no score |
|----------|-------------------|--------------|----------|
| Shape | OVAL | Size | 17mm |
| Flavor | MINT | Imprint Code | AAA;1117 |
| Contains | | | |

| l | Packaging | | | |
|---|------------------|---|-----------------------------|---------------------------|
| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 NDC:50804-828- | 2 in 1 CARTON | 08/01/2017 | |
| ı | 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 | 08/01/2017 | |
| | | | |

Labeler - Goodsense (076059836)

Revised: 12/2018 Goodsense