

**ALLERGY MULTI-SYMPTOM- acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride tablet, coated**  
**STRATEGIC SOURCING SERVICES LLC**

*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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**1128B-FST-2023-0425**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever
Chlorpheniramine maleate 2 mg	Antihistamine
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. 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.

### **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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

### **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)

adults and children 12 years and over	<ul style="list-style-type: none"><li>take 2 caplets every 4 hours</li><li>swallow whole; do not crush, chew, or dissolve</li><li>do not take more than 10 caplets in 24 hours</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>ask a doctor</li></ul>

## Other information

- store between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information and warnings

## Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, flavor, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

## Questions or comments?

Call 833-358-6431

## PRINCIPAL DISPLAY PANEL

NDC 70677-1004-1

Foster & Thrive™

FOR ADULTS

Allergy Multi-Symptom

Acetaminophen 325 mg, Phenylephrine HCl 5 mg, Chlorpheniramine Maleate 2 mg

PAIN RELIEVER, NASAL DECONGESTANT, ANTIHISTAMINE

Cool Taste | May Cause Drowsiness

For relief of:

- Headache • Sinus Pressure
- Nasal Congestion • Runny Nose
- Itchy, Watery Eyes • Sneezing

ACTUAL SIZE

24 CAPLETS

The image shows the back and front panels of a blister pack for Foster & Thrive Allergy Multi-Symptom caplets. The back panel (left) contains detailed drug facts, warnings, and directions. The front panel (right) features the product name, active ingredients, and a list of symptoms it relieves. A small graphic of a caplet is shown with the text 'ACTUAL SIZE'.

**Back Panel (Left):**

- Drug Facts (continued):**
  - When using this product:**
    - drowsiness may occur
    - do not exceed recommended dosage
    - excitability may occur, especially in children
    - avoid alcoholic drinks
    - alcohol, sedatives, and tranquilizers may increase drowsiness
    - be careful when driving a motor vehicle or operating machinery
  - Stop use and ask a doctor if:**
    - nervousness, dizziness, or sleeplessness occur
    - symptoms last 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)
    - adults and children 12 years and over:
      - take 2 caplets every 4 hours
      - swallow whole; do not crush, chew, or dissolve
      - do not take more than 10 caplets in 24 hours
    - children under 12 years:
      - ask a doctor
  - Other information:**
    - this is a prescription drug
    - retain carton for complete product information and warnings
- Drug Facts (continued):**
  - Warnings:**
    - liver damage: 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
    - avoid alcohol while taking this product
    - Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
      - skin redness
      - hives
      - 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.
    - 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:
      - liver disease
      - diabetes
      - heart disease
      - thyroid disease
      - high blood pressure
      - kidney disease
      - asthma
      - 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
  - Inactive ingredients:** acacia, croscarmellose sodium, croscopolone, flavor, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

**Front Panel (Right):**

- Foster & Thrive™ Allergy Multi-Symptom**
- NDC 70677-1004-1
- Foster & Thrive™ FOR ADULTS Allergy Multi-Symptom**
- Acetaminophen 325 mg, Phenylephrine HCl 5 mg, Chlorpheniramine Maleate 2 mg**
- PAIN RELIEVER, NASAL DECONGESTANT, ANTIHISTAMINE**
- Cool Taste | May Cause Drowsiness**
- For relief of:**
  - Headache
  - Sinus Pressure
  - Nasal Congestion
  - Runny Nose
  - Itchy, Watery Eyes
  - Sneezing
- 24 CAPLETS**
- Drug Facts (continued):**
  - headache
  - or other upper respiratory allergies:
  - nasal congestion
  - minor aches and pains
  - runny nose
  - 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
- Drug Facts (continued):**
  - Active ingredients (in each caplet):**
    - Acetaminophen 325 mg.....Pain reliever
    - Chlorpheniramine maleate 2 mg.....Antihistamine
    - Phenylephrine HCl 5 mg.....Nasal decongestant
  - Uses:**
    - temporarily relieves these symptoms of hay fever

## ALLERGY MULTI-SYMP TOM

acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1004
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white (Off-White)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1128
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1004-1	2 in 1 CARTON	04/25/2023	
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	04/25/2023	

**Labeler** - STRATEGIC SOURCING SERVICES LLC (116956644)

