Acetaminophen, Chlorpheniramine Maleate, Dextromethorphan HBr, Phenylephrine HCl 1161

Drug Facts

<table>
<thead>
<tr>
<th>Active ingredients (in each caplet)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 325 mg</td>
<td>Pain reliever</td>
</tr>
<tr>
<td>Chlorpheniramine maleate 2 mg</td>
<td>Antihistamine</td>
</tr>
<tr>
<td>Dextromethorphan HBr 10 mg</td>
<td>Cough suppressant</td>
</tr>
<tr>
<td>Phenylephrine HCl 5 mg</td>
<td>Nasal decongestant</td>
</tr>
</tbody>
</table>

Uses
- temporarily relieves these common cold symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - sneezing and runny nose
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep

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

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
Ask a doctor before use if you have
- liver disease
- high blood pressure
- heart disease
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

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

When using this product
- do not exceed recommended dosage
- excitability may occur, especially in children
- marked 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, 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
Taking more than the recommended dose (overdose) may cause liver damage. 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 12 caplets in 24 hours |
children under 12 years do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

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, FD&C blue #1, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 24 Caplet Blister Pack Carton

RESTORE u
NDC 57344-161-02
†COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® COLD HEAD CONGESTION-NIGHTTIME

NIGHTTIME

Cold HEAD CONGESTION
Pain Reliever, Nasal Decongestant,
Cough Suppressant, Antihistamine
- Headache/Sore Throat – Acetaminophen
- Nasal Congestion – Phenylephrine HCl
- Coughing – Dextromethorphan HBr
- Runny Nose – Chlorpheniramine Maleate

COOL BLAST
24 CAPLETS
### Directions

- Do not exceed the recommended dosage.
- Take at bedtime only if needed.
- Do not take a sedative that contains alcohol or other central nervous system depressants.
- Take only for the symptoms indicated.
- Do not take if you are allergic to any of the ingredients.
- Take as directed.
- Do not exceed the recommended dosage.

### Warnings

- Do not exceed the recommended dosage.
- Do not use if you have had a sensitivity reaction to any ingredient.
- Do not take if you have a history of liver disease.
- Do not take if you are pregnant or breastfeeding.
- Do not use if you have a history of asthma or are allergic to aspirin.

### Drug Facts

- In each tablet:
  - Pain Reliever:
    - Acetaminophen 650 mg
  - Nasal Decongestant:
    - Pseudoephedrine HCl 35 mg
- Each tablet also contains:
  - Calcium Stearate, and others.

### Active Ingredients

- Acetaminophen
- Pseudoephedrine HCl

### Purpose

- Pain Reliever
- Nasal Decongestant

### Precautions

- Do not exceed the recommended dosage.
- Do not take if you have had a sensitivity reaction to any ingredient.
- Do not take if you have a history of liver disease.
- Do not use if you have a history of asthma or are allergic to aspirin.

### Use

- Do not exceed the recommended dosage.
- Do not use if you have had a sensitivity reaction to any ingredient.
- Do not use if you have a history of liver disease.
- Do not use if you have a history of asthma or are allergic to aspirin.

### Storage

- Store at room temperature.
- Keep out of reach of children.

### Distributed by

AA Pharmaceutical, Inc.
Lumberton, NJ 08048

### Nutritional Information

- No sugar, no fat, no sodium.
# ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE

Acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:57344-161</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)</td>
<td>ACETAMINOPHEN</td>
<td>325 mg</td>
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<tr>
<td>CHLORPHENIRAMINE MALEATE (UNII: V1QO09OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)</td>
<td>CHLORPHENIRAMINE MALEATE</td>
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<tr>
<td>DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)</td>
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<td>PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS2976MV)</td>
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## Inactive Ingredients

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<tr>
<td>ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)</td>
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<tr>
<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
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</tr>
<tr>
<td>CROSCARMELLOSE SODIUM (UNII: M280L1H48)</td>
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<tr>
<td>FD&amp;C BLUE NO. 1 (UNII: H3R47K3TBD)</td>
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### MAGNESIUM STEARATE (UNII: 70097M6B0)
### CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
### POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
### POLYVINYL ALCOHOL (UNII: 532BS9J990)
### Povidone (UNII: FZ989GH94E)
### STARCH, CORN (UNII: O8232NY3SJ)
### PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
### STEARIC ACID (UNII: 4ELV7Z65AP)
### Talc (UNII: 7SEV7J4R1U)
### TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

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<tr>
<th>Color</th>
<th>Score</th>
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</thead>
<tbody>
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<table>
<thead>
<tr>
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<table>
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<td>MINT</td>
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### Packaging

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
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<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:57344-161-02</td>
<td>2 in 1 CARTON</td>
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<tr>
<td>1</td>
<td></td>
<td>12 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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### Marketing Information

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<tr>
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<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC monograph final</td>
<td>part341</td>
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### Labeler

- AAA Pharmaceutical, Inc. (181192162)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>AAA Pharmaceutical, Inc.</td>
<td></td>
<td>080164679</td>
<td>manufacture(57344-161)</td>
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<td>pack(57344-161)</td>
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Revised: 12/2018

AAA Pharmaceutical, Inc.