CHILDRENS COLTALIN- acetaminophen, chlorpheniramine maleate, phenylephrine hydrochloride tablet, chewable
FORTUNE PHARMACAL COMPANY LIMITED

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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Drug Facts

Active ingredients (in each tablet)
Acetaminophen 80 mg
Chlorpheniramine maleate 0.5 mg
Phenylephrine hydrochloride 1.25 mg

Purpose
Pain reliever-fever reducer
Antihistamine
Nasal decongestant

Uses
temporarily relieves these symptoms due to a cold, the flu, or hay fever:
sore throat
minor aches and pains
headache
itching of the nose or throat
runny nose
sneezing itchy, watery eyes due to hay fever
sinus congestion and pressure
nasal congestion
temporarily reduces fever
promotes nasal and/or sinus drainage

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes: more than 5 doses in 24 hours, which the maximum daily amount for this product with other drugs containing acetaminophen

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.
in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson’s disease). If you do not know whether a prescription drug contains an MAOI, ask a doctor or pharmacist.
for 2 weeks after stopping the MAOI drug

Ask a doctor before use if the user has
liver disease
heart disease
high blood pressure
thyroid disease
diabetes
glaucoma
a breathing problem such as chronic bronchitis

Ask a doctor or pharmacist before use if the user is
taking the blood thinning drug warfarin
taking sedatives or tranquilizers
taking a prescription drug and you do not know if it contains an MAOI

When using this product
do not exceed recommended dosage
may cause drowsiness (sedatives and tranquilizers may increase the drowsiness effect)
may cause excitability especially in children

Stop use and ask a doctor if
sore throat persists for more than 2 days
sore throat is severe
sore throat is accompanied or followed by: fever, headache, rash, nausea, vomiting
pain or nasal congestion gets worse or lasts more than 5 days
fever gets worse or lasts more than 3 days
redness or swelling is present
new symptoms occur
if nervousness, dizziness, or sleeplessness occur

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

Do not give to children under 6 years of age unless directed by a doctor.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions
children 6 to under 12 years of age: Chew tablet before swallowing. 4 tablets every 4 hours while symptoms persist, not to exceed 5 doses (20 tablets) in 24 hours, or as directed by a doctor
children under 6 of age: consult a doctor

Other information
Phenylketonurics: contains Phenylalanine 4.2mg per tablet
protect from light
store between 15 to 30 C (59 to 86 F)
keep in a dry place

Inactive ingredients
Aspartame, citric acid, corn starch, FDC yellow no. 6 aluminum lake, magnesium stearate, mannitol, pineapple flavor, povidone K30
Questions or comments? (888) 221-3496 M-F 9 am to 5 pm
you may also use this number to report serious adverse events associated with the use of this product

Children's Coltalin
NDC 51467-006-01

Acetaminophen - Pain Reliever-Fever Reducer
Chlorpheniramine maleate - Antihistamine
Phenylephrine hydrochloride- Decongestant

See new warnings information

Sugar Free
Aspirin Free

24 Chewable Tablets

Safety Sealed
Do not use if individually sealed foil unit dose pouches are torn, broken, or shows the evidence of being opened.

### DRUG FACTS

### Active Ingredients (in each Tablet)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>80 mg</td>
</tr>
<tr>
<td>Phenylephrine hydrochloride</td>
<td>1.25 mg</td>
</tr>
<tr>
<td>Chlorpheniramine maleate</td>
<td>5.0 mg</td>
</tr>
</tbody>
</table>

### Uses

- Use to reduce fever in children
- Use as a pain reliever

### Warnings

- Use only as directed
- Do not exceed 4 tablets in 24 hours
- Do not use in children under 12 years of age

### Children's Coltalin

<table>
<thead>
<tr>
<th>Children's Coltalin</th>
<th>NDC 51467-006-01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Sugar Free</td>
</tr>
<tr>
<td>Chlorpheniramine</td>
<td>Aspirin Free</td>
</tr>
<tr>
<td>Phenylephrine</td>
<td>24 Chewable Tablets</td>
</tr>
</tbody>
</table>

### Precautions

- Do not use in children under 12 years of age
- Use as directed
- Do not exceed 4 tablets in 24 hours

### Questions or Comments

(888) 221-3496
M-F 9 am to 5 pm

Do not use if individually sealed foil unit dose pouches are torn, broken, or shows the evidence of being opened.

Manufactured by: Fortune Pharmaceutical Co., Ltd., Hong Kong

*Manufactured in Hong Kong*
**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC: 51467-006</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
<td></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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)</td>
<td>ACETAMINOPHEN</td>
<td>80 mg</td>
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<tr>
<td>CHLORPHENIRAMINE MALEATE (UNII: V1Q009OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)</td>
<td>CHLORPHENIRAMINE MALEATE</td>
<td>0.5 mg</td>
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<tr>
<td>PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)</td>
<td>PHENYLEPHRINE HYDROCHLORIDE</td>
<td>1.25 mg</td>
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**Inactive Ingredients**

<table>
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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>ASPARTAME (UNII: Z0H242BBR1)</td>
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</tr>
<tr>
<td>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)</td>
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<tr>
<td>STARCH, CORN (UNII: 08232NY35J)</td>
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<tr>
<td>FD&amp;C YELLOW NO. 6 (UNII: H77VE83A8)</td>
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<td>MAGNESIUM STEARATE (UNII: 70097M6B0)</td>
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<tr>
<td>MANNITOL (UNII: 3OWL53L36A)</td>
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<td>PINEAPPLE (UNII: 2A88Z0081O)</td>
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### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
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<tbody>
<tr>
<td>orange</td>
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<table>
<thead>
<tr>
<th>Shape</th>
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<tbody>
<tr>
<td>ROUND</td>
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<table>
<thead>
<tr>
<th>Flavor</th>
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<tbody>
<tr>
<td>PINEAPPLE</td>
<td>F;O;R;T;U;N;E</td>
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### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:51467-006-01</td>
<td>24 in 1 CARTON; Type 1: Convenience Kit of Co-Package</td>
<td>03/01/2004</td>
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### Marketing Information

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<tr>
<th>Marketing Category</th>
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<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>OTC monograph final</td>
<td>part341</td>
<td>03/01/2004</td>
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### Labeler
- FORTUNE PHARMACAL COMPANY LIMITED (686280561)

### 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>FORTUNE PHARMACAL COMPANY LIMITED</td>
<td></td>
<td>686280561</td>
<td>manufacture(51467-006)</td>
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</tbody>
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Revised: 11/2019