

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

-----  
**Drug Facts**

**Active ingredients (in each tablet)**

Acetaminophen 325 mg  
Chlorpheniramine maleate 2 mg  
Phenylephrine hydrochloride 5 mg

**Purposes**

Pain reliever-fever reducer  
Antihistamine  
Nasal decongestant

**Uses**

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

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount for this product
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

**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 whether a prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if the user has**

- heart disease
- high blood pressure
- diabetes
- glaucoma

- liver disease
- thyroid disease
- a high fever
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if the user is**

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

**When using this product**

- **do not exceed recommended dosage**
- may cause excitability especially in children
- use caution when driving or operating machinery
- avoid alcoholic beverages
- may cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect

**Stop use and ask a doctor if**

- pain or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)
- sore throat persists for more than 2 days
- fever gets worse or lasts more than 3 days
- nasal congestion is accompanied by fever
- nervousness, dizziness, or sleeplessness occur
- redness or swelling is present
- new symptoms occur
- any of the following occurs (these could be signs of a serious condition):
  - severe sore throat
  - sore throat is accompanied or followed by fever, headache, rash, nausea or vomiting

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

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

**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 for children even if you do not notice any signs or symptoms.

**Directions**

- adults and children 12 years of age and over: take 2 tablets every 4 hours, while symptoms persist, not to exceed 6 doses (12 tablets) in 24 hours, or as directed by a doctor
- children 6 to under 12 years of age: take 1 tablet every 4 hours, while symptoms persist, not to exceed 5 doses (5 tablets) in 24 hours, or as directed by a doctor
- children under 6 years of age : consult a doctor

**Other information**

- keep tightly sealed
- store between below 25 C (77 F) in a dry place, away from direct sunlight

**Inactive ingredients** colloidal silicon dioxide, corn starch, FD&C yellow no. 6 aluminum lake, magnesium stearate, povidone K30, sodium starch glycolate

**Questions or comments? (888) 221-3496 M-F 9 am to 5 pm**

■ you may also report serious side effects to this phone number

COLTALIN

Safely Sealed

NDC 51467-005-01

Acetaminophen - Pain Reliever-Fever Reducer

Chlorpheniramine maleate - Antihistamine

Phenylephrine hydrochloride - Nasal Decongestant

Cold, Flu & Hay Fever Multi-Symptom Relief

■ Minor Aches & Pain, Sore Throat

■ Headache, Fever

■ Nasal Congestion, Sinus Pressure/Drainage

■ Sneezing, Runny Nose

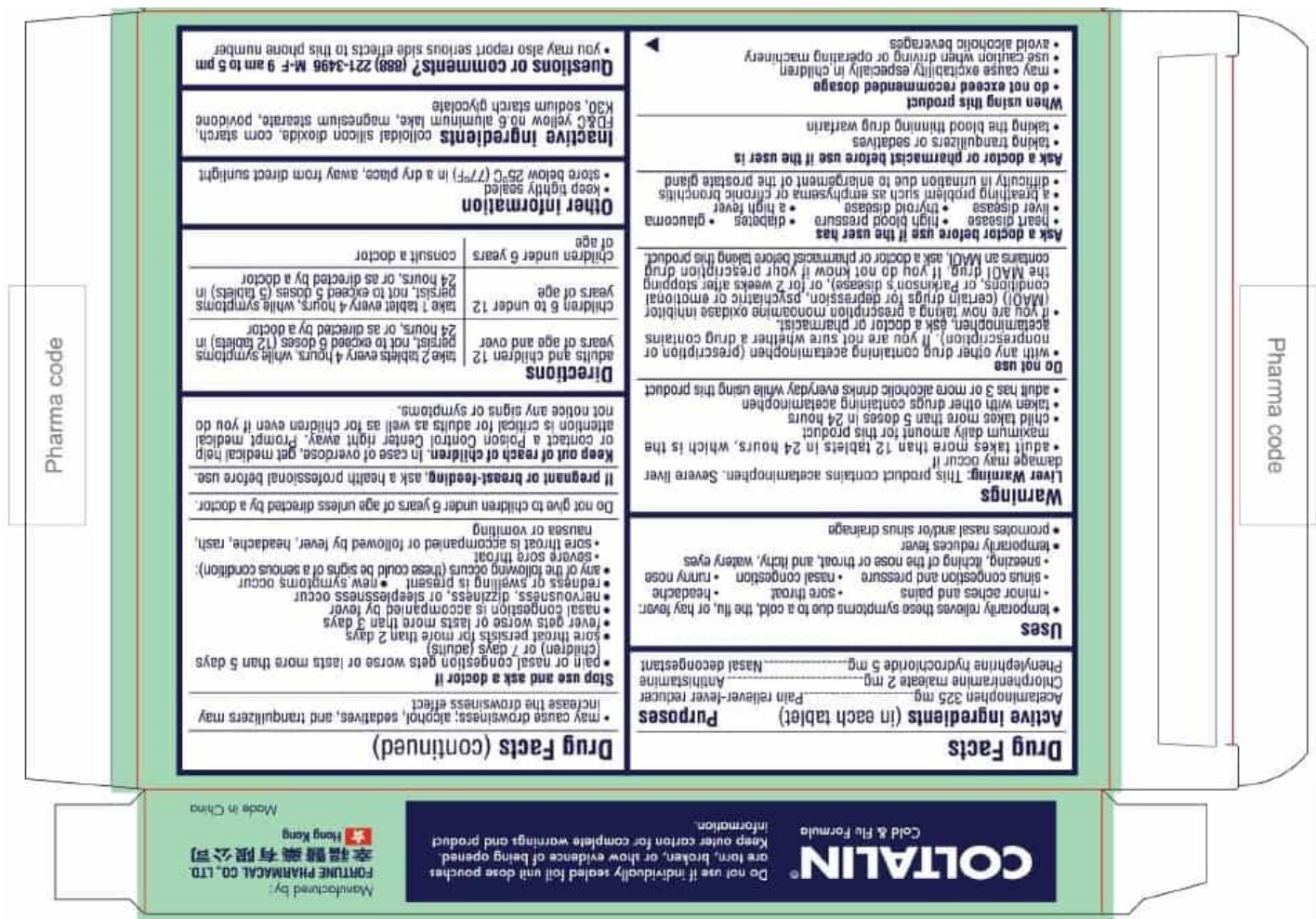
■ Itchy, Watery Eyes

24 Tablets

In Individually Sealed Strip

Aspirin Free





COLTALIN

Safely Sealed

NDC 51467-005-02

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

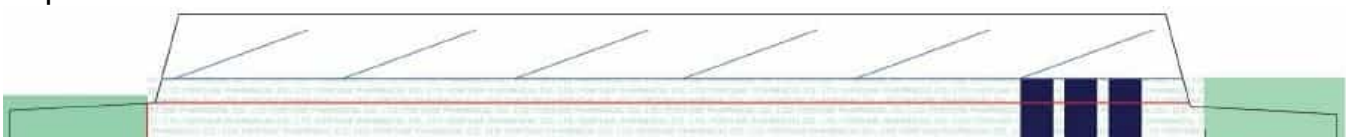
Cold, Flu & Hay Fever Multi-Symptom Relief

- Minor Aches & Pain, Sore Throat
- Headache, Fever
- Nasal Congestion, Sinus Pressure/Drainage
- Sneezing, Runny Nose
- Itchy, Watery Eyes

36 Tablets

In Individually Sealed Strip

Aspirin Free





Product Code

SAFELY SEALED • NDC 51467-005-02

# COLTALIN®

## 幸福傷風素®

Acetaminophen - Pain Reliever - Fever Reducer  
Chlorpheniramine Maleate - Antihistamine  
Phenylephrine Hydrochloride - Nasal Decongestant

Cold, Flu & Hay Fever Multi-Symptom Relief  
傷風、流感、花粉熱 舒緩各種症狀

- Minor Aches & Pain, Sore Throat 輕微疼痛、喉嚨痛
- Headache, Fever 發熱、頭痛
- Nasal Congestion, Sinus Pressure/Drainage 鼻塞、鼻竇充血
- Sneezing, Runny Nose 打噴嚏、流鼻涕
- Itchy, Watery Eyes 眼睛發癢、淚眼



36  
Tablets

In Individually Sealed Strip  
獨立鋁箔密封包裝

ASPIRIN FREE



36 Tablets/H



## 幸福傷風素®

傷風應實配方

Please refer to enclosed package insert for Chinese translation of drug facts.  
請參閱內附之說明書以查看中文藥品資料。

Distributed by:  
**SOI JUSTICE MEDICINE COMPANY**  
美國蘇式藥業有限公司  
215 W. Ave Street  
Los Angeles, CA 90012 U.S.A.  
Tel: (888) 221-3496  
Fax: (323) 221-2448  
[www.soi.com.hk](http://www.soi.com.hk)



**Drug Facts (continued)**

**Stop use and ask a doctor if**  
• pain or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)  
• sore throat persists for more than 2 days  
• fever gets worse or lasts more than 3 days  
• nasal congestion is accompanied by fever  
• fever gets worse or lasts more than 3 days  
• nervousness, dizziness, or sleeplessness occur  
• redness or swelling is present • new symptoms occur  
• any of the following occurs (these could be signs of a serious condition):  
• severe sore throat  
• sore throat is accompanied or followed by fever, headache, rash, nausea or vomiting

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

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

**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 for children even if you do not notice any signs or symptoms.

**Directions**  
adults and children 12 years of age and over: take 2 tablets every 4 hours, while symptoms persist, not to exceed 6 doses (12 tablets) in 24 hours, or as directed by a doctor.  
children 6 to under 12 years of age: take 1 tablet every 4 hours, while symptoms persist, not to exceed 5 doses (5 tablets) in 24 hours, or as directed by a doctor.  
children under 6 years of age: consult a doctor

**Other information**  
• keep tightly sealed  
• store below 25°C (77°F) in a dry place, away from direct sunlight

**Inactive ingredients** colloidal silicon dioxide, corn starch, FD&C yellow no. 6 aluminum lake, magnesium stearate, povidone K30, sodium starch glycolate

**Questions or comments?** (888) 221-3496 M-F 9 am to 5 pm  
• you may also report serious side effects to this phone number

**Drug Facts**

**Active Ingredients (in each tablet)**  
Acetaminophen 325 mg, Pain reliever- fever reducer  
Chlorpheniramine maleate 2 mg, Antihistamine  
Phenylephrine hydrochloride 5 mg, Nasal decongestant

**Purposes**  
Pain reliever- fever reducer  
Antihistamine  
Nasal decongestant

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

**Warnings**  
**Liver Warning:** This product contains acetaminophen. Severe liver damage may occur if:  
• adult takes more than 12 tablets in 24 hours, which is the maximum daily amount for this product  
• child takes more than 5 doses in 24 hours  
• taken with other drugs containing acetaminophen  
• adult has 3 or more alcoholic drinks everyday while using this product

**Do not use**  
• with any other drug containing acetaminophen (prescription or acetaminophen). 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.

**Ask a doctor before use if the user has**  
• heart disease • high blood pressure • diabetes • glaucoma  
• liver disease • thyroid disease • a high fever  
• difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if the user is**  
• taking tranquilizers or sedatives  
• taking the blood thinning drug warfarin

**When using this product**  
• do not exceed recommended dosage  
• use caution when driving or operating machinery  
• avoid alcoholic beverages

Manufactured by:  
**FORTUNE PHARMACEUTICAL CO., LTD.**  
香港藥業有限公司  
Hong Kong  
Made in China

Do not use if individually sealed foil unit dose pouches are torn, broken, or show evidence of being opened.  
Keep outer carton for complete warnings and product information.

# COLTALIN®

Cold & Flu Formula

# COLTALIN

acetaminophen, chlorpheniramine maleate, phenylephrine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51467-005
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	COLTALIN
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-005-01	2 in 1 BOX	03/01/2004	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-005-02	3 in 1 BOX	04/26/2016	
2		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 Drug	M	03/01/2004	

**Labeler** - FORTUNE PHARMACAL COMPANY LIMITED (686280561)

**Registrant** - FORTUNE PHARMACAL COMPANY LIMITED (686280561)

**Establishment**

Name	Address	ID/FEI	Business Operations
FORTUNE PHARMACAL COMPANY LIMITED		686280561	manufacture(51467-005)

Revised: 1/2024

FORTUNE PHARMACAL COMPANY LIMITED