

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

Purpose

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

Directions

- adults and children 12 years of age and over: 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: 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 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 51467-011-01

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



Product code

SAFELY SEALED • NDC 51467-011-01

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

24
Tablets

In Individually Sealed Strip
獨立鋁箔密封包裝

ASPIRIN FREE



MIX
Packaging
FSC® C000000
PRINTED WITH SOY INK

24 Tablets/盒

幸福傷風素®

傷風感冒藥方

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:
SOLSTICE MEDICINE COMPANY
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Fax: (213) 321-2448
www.solsticemedicine.com



Pharma code

Pharma code

Drug Facts (continued)	<p>Stop and ask a doctor if</p> <ul style="list-style-type: none"> • you get worse or lasts more than 5 days (children) or 7 days (adults) • pain or nasal congestion gets worse or lasts more than 5 days • sore throat persists for more than 2 days • fever gets worse or lasts more than 2 days • redness or swelling is present • new symptoms occur • rashes, dizziness, or sleepiness occur • any of the following occurs (these could be signs of a serious condition): <ul style="list-style-type: none"> • severe sore throat • sore throat is accompanied or followed by fever, headache, rash, nausea or vomiting <p>Do not give to children under 6 years of age unless directed by a doctor.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p>
Drug Facts	<p>Active ingredients (in each tablet)</p> <p>Acetaminophen 325 mg - Pain reliever-fever reducer Chlorpheniramine maleate 2 mg - Antihistamine Phenylephrine hydrochloride 5 mg - Nasal decongestant</p> <p>Purposes</p> <p>Temporarily relieves these symptoms due to a cold, the flu, or hay fever:</p> <ul style="list-style-type: none"> • 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 <p>temporarily reduces fever</p> <ul style="list-style-type: none"> • promotes nasal and/or sinus drainage <p>Warnings</p> <p>Liver Warning: This product contains acetaminophen. Severe liver damage may occur if:</p> <ul style="list-style-type: none"> • 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. <p>Do not use</p> <ul style="list-style-type: none"> • with any other drug containing acetaminophen (prescription or over-the-counter) • 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 MAOI drug. If you do not know if you are taking a drug that contains an MAOI, ask a doctor or pharmacist before taking this product. <p>Ask a doctor before use if the user has</p> <ul style="list-style-type: none"> • 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 <p>Ask a doctor or pharmacist before use if the user is</p> <ul style="list-style-type: none"> • taking tranquilizers or sedatives • taking the blood thinning drug warfarin <p>When using this product</p> <ul style="list-style-type: none"> • do not exceed recommended dosage • may cause excitability especially in children • use caution when driving or operating machinery • avoid alcoholic beverages
Directions	<p>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.</p> <p>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.</p> <p>children under 6 years of age: consult a doctor.</p>
Other information	<ul style="list-style-type: none"> • keep tightly sealed • store below 25°C (77°F) in a dry place, away from direct sunlight <p>Inactive ingredients colloidal silicon dioxide, corn starch, FD&C yellow #6, aluminum lake, magnesium stearate, povidone, K3D, sodium starch glycolate</p>
Questions or comments?	<p>• you may also report serious side effects to this phone number: (888) 221-3496 M-F 9 am to 5 pm</p>

Manufactured by:
FORTUNE PHARMACEUTICAL CO., LTD.
幸福藥業有限公司
Hong Kong
Made in China

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

COLTALIN®

Cold & Flu Formula

Version no.

COLTALIN

Safely Sealed

NDC 51467-011-02

Acetaminophen - Pain Reliever-Fever Reducer

Chlorpheniramine maleate - Antihistamine

Phenylephrine hydrochloride - Nasal Decongestant

Cold, Flu & Hay Fever Multi-Symptom Relief

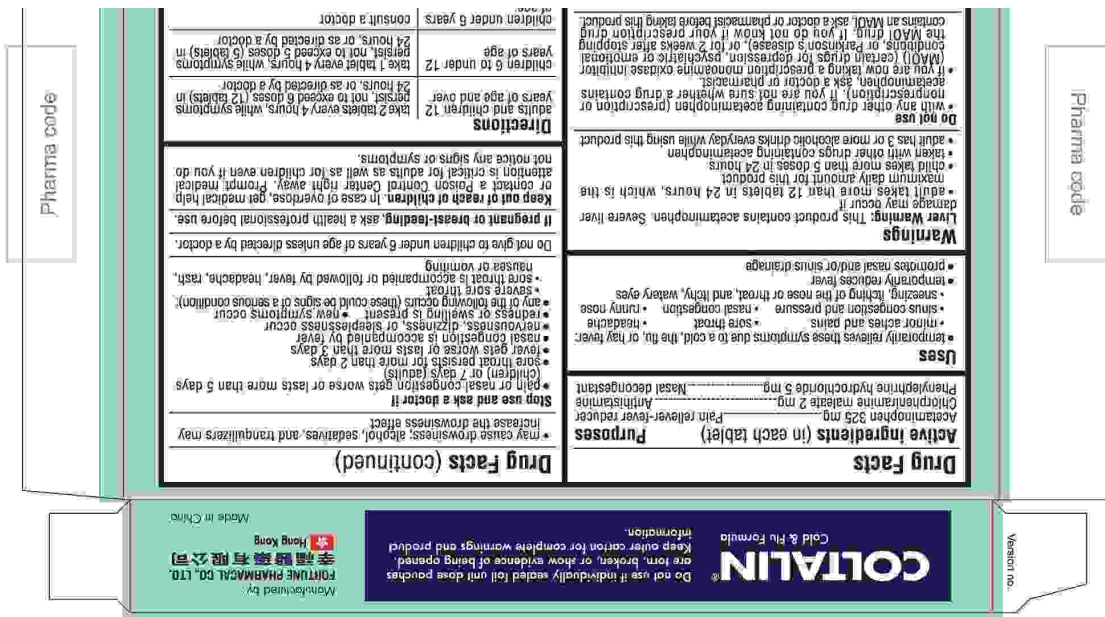
- Minor Aches & Pain, Sore Throat
- Headache, Fever
- Nasal Congestion, Sinus Pressure/Drainage
- Sneezing, Runny Nose
- Itchy, Watery Eyes

36 Tablets

In Individually Sealed Strip

Aspirin Free





COLTALIN

acetaminophen, chlorpheniramine maleate, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51467-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	SHIELDTM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-011-01	2 in 1 BOX	12/26/2024	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-011-02	3 in 1 BOX	12/26/2024	
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	part341	12/26/2024	

Labeler - FORTUNE PHARMACAL COMPANY LIMITED (686280561)

Establishment

Name	Address	ID/FEI	Business Operations
FORTUNE PHARMACAL COMPANY LIMITED		686280561	manufacture(51467-011)

Revised: 12/2024

FORTUNE PHARMACAL COMPANY LIMITED