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

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#### **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:

 $\blacksquare$  adult takes more than 12 tablets in 24 hours, which 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
- $\blacksquare$  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



- E					
		Questions or comments? (888) 221-3496 M-F 9 am to 5 pm • you may also report serious side effects to this phone number	<ul> <li>Invoid alcoholic baverages</li> <li>Inse cantion when dravid or oberation machinery</li> <li>Inse cantion when dravid or oberation in conjudent</li> <li>In or acceed recommended dosage</li> </ul>		
		Inactive ingredients colloidal allicon dioxida, com atarch, FD&C yellow no.6 aluminum lake, magnesium stearate, povidone K30, sodium starch piycolaite	kak a doctor or pharmaciat tectore use if the user is - taking tranguilizers or sadatives - taking the biod thinning drug wartarin When using this product		
		Other information + each tighty sealed + sore below 25°C (779F) in a dry place, away from direct sunlight + sore below 25°C (779F) in a dry place, away from direct sunlight	Ask a doctor before use if the user has + hear disease they problem such as emphysema or chonchils • a breathing problem such as emphysema or chonch bronchils • a difficulty in unnation due to anlargement of the prostate gland • difficulty in unnation due to anlargement of the prostate gland		
		children under 6 years consult a doctor	contains an MUU, ask a doctor or pharmacist before taking this product.		
		children 6 to under 12 take 1 tablet every 4 hours, while symptoms persis of age 24 hours, or exceed 5 doses (5 tablets) in 24 hours, or ex directed by a doctor	Our hot may other drug containing acetaminophen (prescription or normal may other drug containing acetaminophen (prescription or normal may other drug contains a drug or the prescription (model) (certain drug or depression, psychiatric or emotional the MACII (drug, II you do nor pression, psychiatric or emotional the MACII) (certain drug or depression, psychiatric or emotional the MACII (drug, II you do nor pression, psychiatric or emotional the MACII (drug, II you do nor pression, psychiatric or emotional the MACII (drug, II you do nor know if your prescription drug the product.		-
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		(childran) or for days days sort throat persists for more than 2 days ever gots wore or lasts more than 2 days ever gots of swithing is accompanied by fever, headache, rash, ever gots or swithing is present ever persons occur ever gots for swithing is present ever persons occur ever gots for swithing is present ever persons occur any of the following occurs (free could be signe of a across occur ever gots for throat is encompanied or followed by fever, headache, rash, sore throat is encompanied or followed by fever, headache, rash, sore throat is encompanied or followed by fever, headache, rash, ansea or vomiting throat and the shittener mater is wing of appreciate disease the dasher throat and the second be the second be appreciated a second second throat is encompanied or followed by fever, headache, rash, ansea or vomiting throat and the second be appreciated a second second throat and the second second be appreciated a second second the second second be appreciated a second second second the second second be appreciated a second second second second second second second second second second the second sec	USes • temporarity relieves these symptoms due to a cold, the flu, or hay feven: • temporarity relieves these symptoms due to a cold, the flu, or hay feven: • ainus congestion and pressure • anexing, inching of the noes or throat, and licity, watery eyes • temporarity reduces feven: • promotes nasal and/or sinus drainage		
		Stop use and ask a doctor it solin or nead concestion dets worse or leafs more then 5 days	Acelaminophen 325 mg		
		<ul> <li>may cause drowsiness; alcohol, sodatives, and tranquilizers may inclease the drowsiness effect</li> </ul>	Active ingredients (in each tablet) Purposes		
		Drug Facts (continued)	Drug Facts		
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## COLTALIN

Safely Sealed

NDC 51467-005-02

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

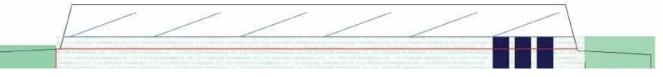
Cold, Flu & Hay Fever Multi-Symptom Relief

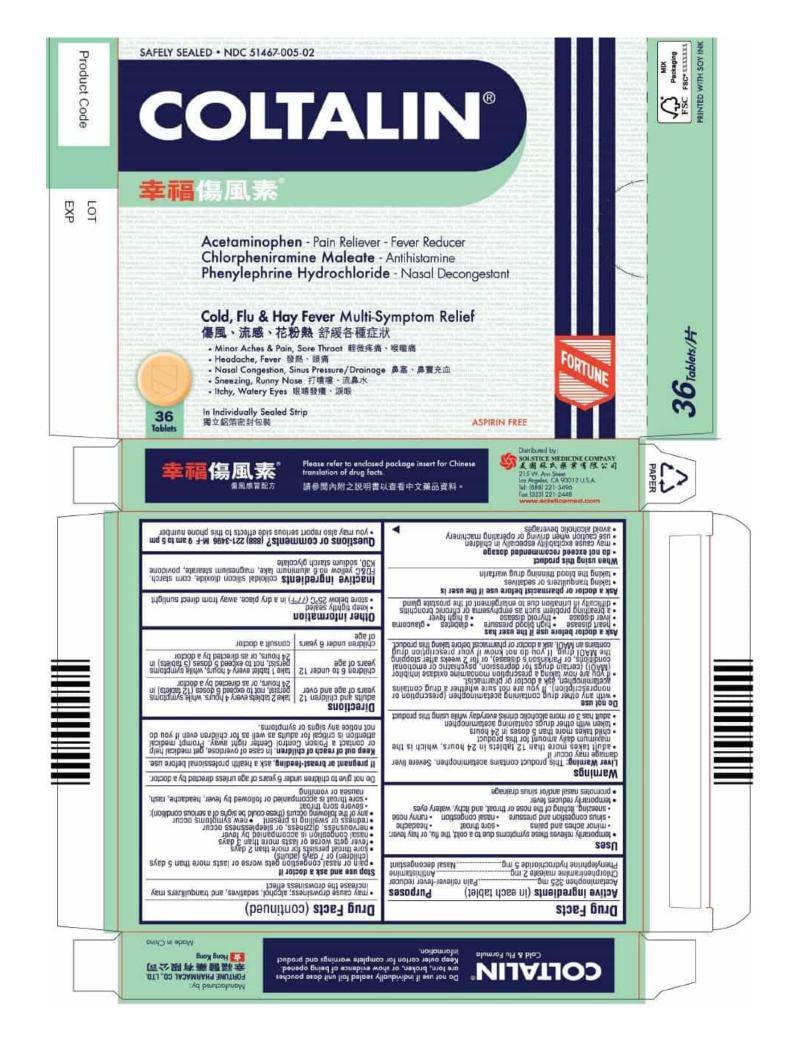
- Minor Aches & Pain, Sore Throat
- Headache, Fever
- Nasal Congestion, Sinus Pressure/Drainage
- Sneezing, Runny Nose
- Itchy, Watery Eyes

36 Tablets

In Individually Sealed Strip

Aspirin Free





# COLTALIN

acetaminophen, chlorpheniramine maleate, phenylephrine hydrochloride tablet

Product Type		HUMAN O	TC DRUG	Item Code (	Code (Source)		NDC:51467-005		
Route of Admin	istration	ORAL							
Active Ingred	lient/Act	ive Moiety							
		igredient Na			Basis of St	rength	Strengt		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209 CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRA					ACETAMINOPHEN		325 mg		
JNII:3U6I01965U)	IINE MALE	AIE (UNII: VIQU	090J92) (CHLO	RPHENIRAMINE -	CHLORPHENIRAM MALEATE	IINE	2 mg		
PHENYLEPHRINE JNII:1WS297W6MV)	LORIDE (UNII: 0	4ja59tnsj) (Phi	NSJ) (PHENYLEPHRINE - PHENYLEPHRINE HYDROCHLORIDI			5 mg			
Inactive Ingro	odionte								
nactive night	culents	Ingre	edient Name				Strength		
SILICON DIOXIDE	(UNII: ETI7	•					2 a chg th		
STARCH, CORN (L									
FD&C YELLOW N	<b>0.6</b> (UNII:	H77VEI93A8)							
MAGNESIUM STE	ARATE (UN	II: 70097M6I30)							
POVIDONE K30 (U	JNII: U725Q	POVIDONE K30 (UNII: U725QWY32X)							
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)									
SODIUM STARCH	GLYCOLA	ТЕ ТҮРЕ А РОТ	<b>ATO</b> (UNII: 585	6J3G2A2)					
SODIUM STARCH	GLYCOLA	ТЕ ТҮРЕ А РОТ	<b>`ATO</b> (UNII: 585	6J3G2A2)					
			<b>'ATO</b> (UNII: 585	6J3G2A2)					
Product Char			ATO (UNII: 585	6J3G2A2)	nc	) score			
<b>Product Char</b> <sup>Color</sup>		ics		6J3G2A2)		o score 2mm			
<b>Product Char</b> Color Shape		<b>ics</b> orange	Score		12				
<b>Product Char</b> Color Shape Flavor		<b>ics</b> orange	Score Size		12	2mm			
SODIUM STARCH <b>Product Char</b> Color Shape Flavor Contains		<b>ics</b> orange	Score Size		12	2mm			
<b>Product Char</b> Color Shape Flavor Contains		<b>ics</b> orange	Score Size		12	2mm			
<b>Product Char</b> Color Shape Flavor Contains		<b>ics</b> orange	Score Size	Code	12 CC	2mm DLTALIN			
Product Char Color Shape Flavor Contains Packaging		<b>ics</b> orange	Score Size Imprint (	Code	12	2mm OLTALIN Marke	eting End Date		
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Product Char Color Shape Flavor Contains Packaging # Item Code	acterist	ics orange ROUND	Score Size Imprint (	Code Mar 03/01/	tketing Start Date	2mm OLTALIN Marke	-		
Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:51467- 005-01	2 in 1 BO 12 in 1 BL Product 3 in 1 BO	ics orange ROUND Package D X ISTER PACK; Typ	escription	Code Mar 03/01/ hbination 04/26/	12         Co         *keting Start         Date         2004	2mm OLTALIN Marke	-		
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Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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	<b>Business Operations</b>
FORTUNE PHARMACAL COMPANY LIMITED		686280561	manufacture(51467-005)

Revised: 1/2024

FORTUNE PHARMACAL COMPANY LIMITED