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

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# **Drug Facts**

**Active ingredients**(in each tablet) Acetaminophen 325 mg Phenylephrine hydrochloride 5 mg

# Purpose

Pain reliever-fever reducer 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
- temporarily reduces fever

# 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. for fever for more than 3 days, unless directed by a physician

■ 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
- difficulty in urination due to enlargement of the prostate gland

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

- taking the blood thinning drug warfarin
- taking a prescription drug and you do not know if it contains an MAOI

#### When using this product

#### do not exceed recommended dosage

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

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, FDC red no. 40 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-ND

Non-Drowsy

Safely Sealed

NDC 51467-008-01

Acetaminophen - Pain Reliever-Fever Reducer Phenylephrine Hydrochloride - Nasal Decongestant

Cold, Flu & Hay Fever Multi-Symptom Relief

- Minor Aches & Pain, Sore Throat
- Headache, Fever

■ Nasal Congestion, Sinus Pressure/Drainage

24 Tablets

In Individually Sealed Strip

Aspirin Free





COLTALIN-ND

Non-Drowsy

Safely Sealed

NDC 51467-008-02

Acetaminophen - Pain Reliever-Fever Reducer Phenylephrine Hydrochloride - Nasal Decongestant

Cold, Flu & Hay Fever Multi-Symptom Relief ■ Minor Aches & Pain, Sore Throat

Headache, Fever

Nasal Congestion, Sinus Pressure/Drainage

36 Tablets In Individually Sealed Strip

Aspirin Free





COLTALIN-	ND									
acetaminophen,	phenylephri	ine hydrochlor	ride tablet							
Product Info	rmation									
Product Type		HUMAN OTC D	RUG	Item Code (Source)			NDC:514	NDC:51467-008		
Route of Admin	istration	ORAL								
Active Ingredient/Active Moiety										
	-	edient Name				Basis of Strength		Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209I							325 mg			
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRI UNII:1WS297W6MV)						HENYLEPHRIN IYDROCHLORII		5 mg		
Inactive Ingredients										
Ingredient Name								Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)										
STARCH, CORN (UNII: 08232NY3SJ)										
FD&C RED NO. 40 (UNII: WZB9127XOA) MAGNESIUM STEARATE (UNII: 70097M6I30)										
POVIDONE K30 (UNII: U725QWY32X)										
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)										
Product Char			_							
Color	k	Score				no score				
Shape ROU		UND	Size				12mm FORTUNE			
Flavor			Imprint Code				FORTONE			
Contains										
Packaging										
# Item Code	Pa	ackage Desci	ription	M	1ark	eting Start Date		eting End Date		
<b>1</b> NDC:51467- 008-01	2 in 1 BOX			03/	/01/20					
1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product			pination						
<b>2</b> NDC:51467- 008-02	3 in 1 BOX			04/	/26/20	916				
<b>`</b>	12 in 1 BLISTE	ER PACK; Type 0:	Not a Comb	pination						

2 Pi	roduct								
Marketing Information									
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
OTC Monograph Drug	part341	03/01/2004							

Labeler - FORTUNE PHARMACAL COMPANY LIMITED (686280561)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
FORTUNE PHARMACAL COMPANY LIMITED		686280561	manufacture(51467-008)

Revised: 11/2024

FORTUNE PHARMACAL COMPANY LIMITED