

**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

- 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

**Allergy alert:** Acetaminophen may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If a skin rash occurs, stop use and seek medical help right away.

**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**

Citric Acid Monohydrate, Hydroxypropyl Methylcellulose, Corn starch, Microcrystalline Cellulose, FD&C red no. 40 aluminum lake, Colloidal silicon dioxide, Magnesium stearate, 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 51467-013-01

Acetaminophen - Pain Reliever-Fever Reducer

Phenylephrine Hydrochloride - Nasal Decongestant

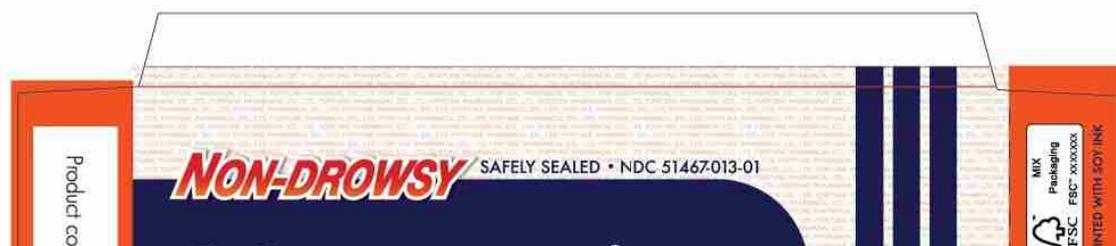
Cold, Flu & Hay Fever Multi-Symptom Relief

- Minor Aches & Pain, Sore Throat
- Headache, Fever
- Nasal Congestion, Sinus Pressure/Drainage

24 Tablets

In Individually Sealed Strip

Aspirin Free



LOT  
EXP

# COLTALIN-ND

## 無睡意幸福傷風素

Acetaminophen - Pain Reliever - Fever Reducer  
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

**24 Tablets**  
獨立鋁箔密封包裝

ASPIRIN FREE

24 Tablets/片

**無睡意  
幸福傷風素**

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:  
**SOLESTEC MEDICINE COMPANY**  
索士德醫藥有限公司  
315 W. Ave. 100  
Los Angeles, CA 90013 U.S.A.  
Tel: (818) 221-3486  
Fax: (818) 221-2448  
www.coltalin.com/medic.com

PAPER

Pharma code

**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 is accompanied or followed by:
  - vomiting
  - nausea
  - rash
  - headache
  - 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 persists or gets worse
    - rash or swelling is present

**Warnings** 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

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness • blisters • rash

If a skin reaction occurs, stop use and seek medical help right away.

**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) or 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**

- 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

Pharma code

Manufactured by  
SOLESTEC PHARMACEUTICAL CO., LTD.  
索士德藥業有限公司  
Hong Kong  
Made in China

**COLTALIN-ND**  
Non-Drowsy

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.

Version no.

COLTALIN-ND

Non-Drowsy

Safely Sealed

NDC 51467-013-02

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

Product code

**NON-DROWSY** SAFELY SEALED • NDC 51467-013-02

# COLTALIN<sup>®</sup>-ND

無睡意幸福傷風素<sup>®</sup>

Acetaminophen - Pain Reliever - Fever Reducer  
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

36 Tablets  
In Individually Sealed Strip  
獨立鋁箔密封包裝

ASPIRIN FREE

MIX Packaging  
FSC® x0xxxxx  
PRINTED WITH SOY INK

LOT  
EXP

36 Tablets / 盒

**FORTUNE**

PAPER

無睡意  
幸福傷風素<sup>®</sup>

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  
**SOUTHEAST MEDICINE COMPANY**  
東南藥業有限公司  
215 W. Ave. Ste. 200  
Los Angeles, CA 90012 U.S.A.  
Tel: (818) 221-3456  
Fax: (323) 221-2448  
www.coltalinmed.com

Pharma code

<p><b>Warnings</b> - This product contains acetaminophen. Severe liver damage may occur if:</p> <ul style="list-style-type: none"> <li>• minor aches and pains • sore throat • headache</li> <li>• sinus congestion and pressure • nasal congestion</li> <li>• temporarily reduces fever</li> </ul> <p><b>Adverse Reactions</b> - This product contains acetaminophen. Severe skin reactions may include:</p> <ul style="list-style-type: none"> <li>• skin redness • skin peeling • blisters • rash</li> </ul> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Adult has 3 or more allergic drug reactions using this product.</p> <ul style="list-style-type: none"> <li>• taken with other drugs containing acetaminophen</li> <li>• child takes more than 5 doses in 24 hours</li> <li>• maximum daily amount for this product</li> <li>• adult takes more than 12 tablets in 24 hours, which is the maximum daily amount for this product.</li> </ul> <p><b>Liver Warnings:</b> This product contains acetaminophen. Severe liver damage may occur if:</p> <ul style="list-style-type: none"> <li>• adult takes more than 12 tablets in 24 hours, which is the maximum daily amount for this product.</li> <li>• child takes more than 5 doses in 24 hours</li> <li>• maximum daily amount for this product</li> </ul> <p><b>Do not use</b> if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</p> <p><b>Do not use</b> if you are now taking a prescription, psychiatric or emotional (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.</p> <p><b>Ask a doctor before use if the user has:</b></p> <ul style="list-style-type: none"> <li>• heart disease • high blood pressure • diabetes</li> <li>• liver disease • thyroid disease • a high fever</li> <li>• difficulty in urination due to enlargement of the prostate gland</li> </ul> <p><b>Ask a doctor or pharmacist before use if the user is:</b></p> <ul style="list-style-type: none"> <li>• taking the blood thinning drug warfarin</li> <li>• taking a prescription drug and you do not know if it contains an MAOI</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• do not exceed recommended dosage</li> </ul>	<p><b>Directions</b></p> <p>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> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• keep tightly sealed</li> <li>• store below 25°C (77°F) in a dry place, away from direct sunlight</li> </ul> <p><b>Inactive ingredient</b> Citric Acid Monohydrate, Hydroxypropyl Methylcellulose, Carnauctin, Macroglyme Cellulose, FD&amp;C Red No. 40, Aluminum Lake, Colloidal silicon dioxide, Magnesium stearate, Sodium Starch Glycolate.</p> <p><b>Questions or comments?</b> (888) 221-3456 M-F 9 am to 5 pm • you may also report serious side effects to this phone number</p>
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Pharma code



## COLTALIN-ND

acetaminophen, phenylephrine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51467-013
<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>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>HYDROXYPROPYL METHYLCELLULOSE</b> (UNII: 3NXW29V3WO)	

### Product Characteristics

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-013-01	2 in 1 BOX	01/30/2026	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-013-02	3 in 1 BOX	01/30/2026	
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	M012	01/30/2026	

**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(51467-013)

Revised: 2/2026

FORTUNE PHARMACAL COMPANY LIMITED