

**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

**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 51467-013-01

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

**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

In Individually Sealed Strip  
 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。

INDUSTRIAL MEDICAL PRODUCTS COMPANY  
 工業藥材有限公司  
 1100 West Beaver Creek Road  
 Richmond Hill, Ontario L4B 3N2  
 Tel: (905) 882-8888  
 Fax: (905) 882-8889  
 www.industrialmed.com



Pharma code

Pharma code

<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• pain or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)</li> <li>• sore throat is severe</li> <li>• sore throat persists for more than 2 days</li> <li>• fever is accompanied or followed by:</li> <li>• fever • headache • rash • nausea • vomiting</li> <li>• nervousness, dizziness, or sleeplessness occur</li> <li>• fever gets worse or lasts more than 3 days</li> <li>• any of the following occurs (these could be signs of a serious condition):</li> <li>• new symptoms occur</li> <li>• pain or fever persists or gets worse</li> <li>• redness or swelling is present</li> </ul> <p>Do not give to children under 6 years of age unless directed by a doctor.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical help is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions</b></p> <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 3 doses (6 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 lightly sealed</li> <li>• store below 25°C (77°F) in a dry place, away from direct sunlight</li> <li>• store in original container</li> </ul> <p><b>Inactive ingredients</b></p> <p>colloidal silicon dioxide, corn starch, FD&amp;C red no. 40 aluminum lake, magnesium stearate, povidone K30, sodium starch glycolate</p> <p><b>Questions or comments?</b> (888) 221-3496 M-F 9 am to 5 pm          • you may also report serious side effects to this phone number</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each tablet)</b></p> <p>Acetaminophen 325 mg              Pain reliever-fever reducer</p> <p>Phenylephrine hydrochloride 5 mg              Nasal decongestant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• temporarily relieves these symptoms due to a cold, the flu, or hay fever:</li> <li>• minor aches and pains</li> <li>• sinus congestion and pressure</li> <li>• sore throat</li> <li>• headache</li> <li>• temporarily reduces fever</li> </ul> <p><b>Warnings</b></p> <p><b>Liver Warning:</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>• taken with other drugs containing acetaminophen</li> <li>• adult has 3 or more alcoholic drinks everyday while using this product</li> </ul> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>• 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 contains an MAOI, ask a doctor or pharmacist before taking this product.</li> </ul> <p><b>Ask a doctor before use if the user has</b></p> <ul style="list-style-type: none"> <li>• heart disease</li> <li>• thyroid disease</li> <li>• diabetes</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>
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INDUSTRIAL MEDICAL PRODUCTS COMPANY  
 工業藥材有限公司  
 1100 West Beaver Creek Road  
 Richmond Hill, Ontario L4B 3N2  
 Tel: (905) 882-8888  
 Fax: (905) 882-8889  
 www.industrialmed.com

**NON-DROWSY**  
**COLTALIN-ND**

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 06

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 51467013-02

# COLTALIN<sup>®</sup>-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

In Individually Sealed Strip  
獨立鋁箔密封包裝

ASPIRIN FREE

MIX Packaging FSC® XXXXXX

PROBEC WITH SOY INK

36 Tablets/盒

LOT  
EXP

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。

SOLE SOURCE MEDICINE COMPANY  
大洲藥業有限公司  
17000 170th Ave S.  
Burien, WA 98148  
Tel: (206) 835-1833  
www.coltalin.com

Pharma code

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

**Uses**  
temporarily relieves these symptoms due to cold, the flu, or hay fever:  
• minor aches and pains  
• sore throat  
• sinus congestion and pressure  
• nasal congestion

**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 every day 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 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  
• liver disease • thyroid disease  
• 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

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

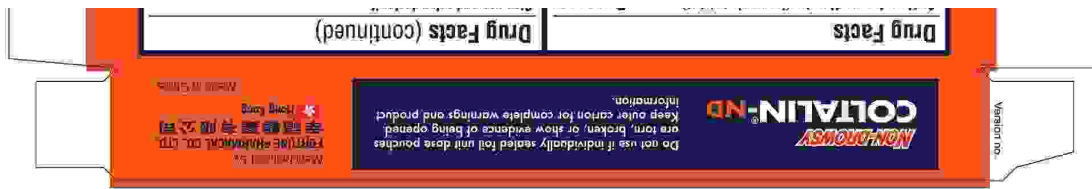
**Directions**  
adults and children 12 years of age and over: take 2 tablets every 4 hours, while symptoms persist, not to exceed 6 doses (12 tablets) in 24 hours, or as directed by a doctor  
children 6 to under 12 years of age: take 1 tablet every 4 hours, while symptoms persist, not to exceed 5 doses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

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

**Active Ingredients**  
coloidal silicon dioxide, corn starch, K99, sodium starch glycolate

**Questions or comments?** (888) 221-3498, M-F 9 am to 5 pm  
• you may also report serious side effects to this phone number

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>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: 70097M6I30)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

### 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	12/26/2024	

1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-013-02	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(51467-013)

Revised: 12/2024

FORTUNE PHARMACAL COMPANY LIMITED