

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

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 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



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。

Distributed by
SOUSTICE MEDICAL COMPANY
美國蘇士德醫藥有限公司
215 W. Ann Drive
Los Angeles, CA 90017 U.S.A.
Tel: (800) 221-3666
Fax: (213) 972-2648
www.soustice.com

<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • 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 • sore throat is severe • fever gets worse or lasts more than 3 days • any of the following occurs (these could be signs of a serious condition): <ul style="list-style-type: none"> • 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): <ul style="list-style-type: none"> • new symptoms occur • pain or fever persists or gets worse • redness or swelling is present • pain or fever persists or gets worse <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. From prompt medical help, attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <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>Drug Facts</p> <p>Active Ingredients (in each tablet)</p> <p>Acetaminophen 325 mg Pain reliever- fever reducer</p> <p>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 • sinus congestion and pressure • nasal congestion <p>Temporarily reduces fever</p> <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 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. <p>Ask a doctor before use if the user has</p> <ul style="list-style-type: none"> • diabetes • liver disease • heart disease • thyroid disease • a high fever • 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 the blood thinning drug warfarin <p>When using this product</p> <ul style="list-style-type: none"> • do not exceed recommended dosage • taking a prescription drug and you do not know if contains an MAOI
<p>Directions</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 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>Other Information</p> <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</p> <p>FD&C red no. 40 aluminum lake, magnesium stearate, corn starch, K30, sodium starch glycolate</p> <p>Questions or comments? (888) 221-3496 M-F 9 am to 5 pm</p> <p>*you may also report serious side effects to this phone number</p>

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

Version 1.0

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.

Manufactured by
FORTUNE PHARMACAL CO. LTD.
幸福醫藥有限公司
Hong Kong

Made in China

Product code

NON-DROWSY SAFELY SEALED • NDC 51467-008-02

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

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- 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

紫風樓牌特製無
NON-DROWSY
COLTALIN-ND

36

Tablets/片

LOT
EXP

無睡意
幸福傷風素

Please refer to enclosed package insert for Chinese translation of drug facts.
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Distributed by
SPHINX MEDICAL COMPANY
美國科森醫藥有限公司
315 W. Ann Street
Los Angeles, CA 90017 U.S.A.
Tel: (800) 271-5800
Fax: (213) 241-0444
www.sphinxmed.com

Drug Facts (continued)

Drug Facts

Active Ingredients (in each tablet)
Acetaminophen 325 mg
Pain reliever- fever reducer (ibuprofen) 7 days (tablets)
Phenylephrine hydrochloride 5 mg
Nasal decongestant

Purposes
• temporarily relieves these symptoms due to a cold, the flu, or hay fever:
• minor aches and pains
• sore throat
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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
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• 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.
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Ask a doctor before use if the user has
• heart disease • high blood pressure • diabetes • difficulty in urination due to enlargement of the prostate gland
Ask a doctor or pharmacist before use if the user is
• taking a prescription drug and you do not know if it contains an MAOI
• taking the blood thinning drug warfarin
When using this product
• do not exceed recommended dosage

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you may also report serious side effects to the phone number

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Directions
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children under 6 years of age
consult a doctor

Other information

Other information
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• store below 25°C (77°F) in a dry place, away from direct sunlight
Inactive ingredients
colloidal silicon dioxide, corn starch, FD&C red no. 40, aluminum lake, magnesium stearate, polydione K30, sodium starch glycolate

Questions or comments? (888) 221-3466 M-F 9 am to 5 pm
you may also report serious side effects to the phone number

Keep out of reach of children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center for adults as well as for children even if you do not notice any signs or symptoms.

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.

Warnings
• pain or fever persists or gets worse
• redness or swelling is present
• new symptoms occur
• any of the following occurs (these could be signs of a serious condition):
• fever • headache • rash • nausea • vomiting
• nervousness, dizziness, or sleeplessness occur
• fever gets worse or lasts more than 3 days
• sore throat persists for more than 2 days
• sore throat is accompanied or followed by:
• sore throat persists for more than 7 days (adults) or 7 days (children)
• pain or nasal congestion gets worse or lasts more than 5 days

Stop use and ask a doctor if

COLTALIN-ND

acetaminophen, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51467-008
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FORTUNE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-008-01	2 in 1 BOX	03/01/2004	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-008-02	3 in 1 BOX	04/26/2016	
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	03/01/2004	

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(51467-008)

Revised: 11/2025

FORTUNE PHARMACAL COMPANY LIMITED