

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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



LOT
EXP

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

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
SOULAGE MEDICINE COMPANY
美國科林氏藥業有限公司
13377 Van Ness
San Francisco, CA 94133 U.S.A.
Tel: (415) 221-5888
Fax: (415) 221-2648
www.colinmedicine.com

Drug Facts

| | |
|---|---|
| <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 • fever, headache, rash, or 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 <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>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (From medical help, attention is critical for adults as well as for children even if you do not notice any signs or symptoms.)</p> <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 5 doses (5 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 colloidal silicon dioxide, corn starch, FD&C red no. 40 aluminum lake, magnesium stearate, povidone, K30, sodium starch glycolate</p> <p>Questions or comments? (888) 221-3496 M-F 9 am to 5 pm • you may also report serious side effects to this phone number</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>Uses</p> <ul style="list-style-type: none"> • temporarily relieves these symptoms due to a cold, the flu, or hay fever: <ul style="list-style-type: none"> • minor aches and pains • sore throat • sinus congestion and pressure • nasal congestion • temporarily reduces fever <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"> • heart disease • high blood pressure • a high fever • liver disease • thyroid disease • 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 a prescription drug and you do not know if it contains an MAOI <p>When using this product</p> <ul style="list-style-type: none"> • do not exceed recommended dosage |
|---|---|

- 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.
幸福藥業有限公司
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[®]

無睡意幸福傷風素
NON-DROWSY COLTALIN[®]-ND

LOT
EXP

Acetaminophen - Pain Reliever - Fever Reducer
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Cold, Flu & Hay Fever Multi-Symptom Relief
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獨立鋁箔密封包裝

ASPIRIN FREE

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無睡意
幸福傷風素[®]

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Distributed by
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美國純臣醫學有限公司
315 W. Ann Street
Los Angeles, CA 90017 U.S.A.
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Fax: (213) 521-0244
www.softicemed.com

Drug Facts

USES

Temporarily relieves these symptoms due to a cold, the flu, or hay fever:

- minor aches and pains
- sore throat
- nasal congestion
- sinus congestion and pressure
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if:

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Ask a doctor before use if the user has

- diabetes
- heart disease
- high blood pressure
- liver disease
- thyroid disease
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- do not exceed recommended dosage

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children under 6 years of age: consult a doctor.

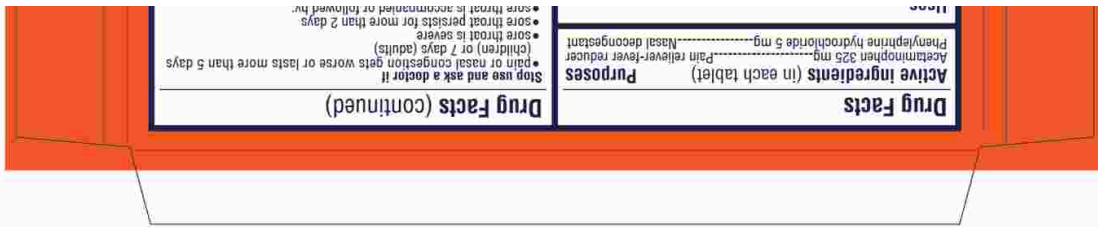
Other information

- keep tightly sealed.
- store below 25°C (77°F) in a dry place, away from direct sunlight.

Inactive ingredients colloidal silicon dioxide, magnesium stearate, corn starch, FD&C red no. 40 aluminum lake, magnesium stearate, povidone, K50, 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

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 | | |

| | | | | |
|---|------------------|---|------------|--|
| 1 | | 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 final | part341 | 03/01/2004 | |

Labeler - FORTUNE PHARMACAL COMPANY LIMITED (686280561)

Establishment

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

Revised: 2/2021

FORTUNE PHARMACAL COMPANY LIMITED