

**CHILDRENS COLTALIN- acetaminophen, chlorpheniramine maleate,
phenylephrine hydrochloride tablet, chewable
FORTUNE PHARMACAL COMPANY LIMITED**

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 80 mg

Chlorpheniramine maleate 0.5 mg

Phenylephrine hydrochloride 1.25 mg

Purpose

Pain reliever-fever reducer

Antihistamine

Nasal decongestant

Uses

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

sore throat

minor aches and pains

headache

itching of the nose or throat

runny nose

sneezing itchy, watery eyes due to hay fever

sinus congestion and pressure

nasal congestion

temporarily reduces fever

promotes nasal and/or sinus drainage

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes: more than 5 doses in 24 hours, which the maximum daily amount for this product

with other drugs containing acetaminophen

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.

in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease). If you do not know whether a prescription drug contains an MAOI, ask a doctor or pharmacist.

for 2 weeks after stopping the MAOI drug

Ask a doctor before use if the user has
liver disease
heart disease
high blood pressure
thyroid disease
diabetes
glaucoma
a breathing problem such as chronic bronchitis

Ask a doctor or pharmacist before use if the user is
taking the blood thinning drug warfarin
taking sedatives or tranquilizers
taking a prescription drug and you do not know if it contains an MAOI

When using this product
do not exceed recommended dosage
may cause drowsiness (sedatives and tranquilizers may increase the drowsiness effect)
may cause excitability especially in children

Stop use and ask a doctor if
sore throat persists for more than 2 days
sore throat is severe
sore throat is accompanied or followed by: fever, headache, rash, nausea, vomiting
pain or nasal congestion gets worse or lasts more than 5 day
fever gets worse or lasts more than 3 days
redness or swelling is present
new symptoms occur
if nervousness, dizziness, or sleeplessness occur

If pregnant or breast-feeding, ask a health professional before use.

Do not give to children under 6 years of age unless directed by a doctor.

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

children 6 to under 12 years of age: Chew tablet before swallowing. 4 tablets every 4 hours while symptoms persist, not to exceed 5 doses (20 tablets) in 24 hours, or as directed by a doctor
children under 6 of age : consult a doctor

Other information

Phenylketonurics: contains Phenylalanine 4.2mg per tablet
 protect from light
 store between 15 to 30 C (59 to 86 F)
 keep in a dry place

Inactive ingredients

Aspartame, citric acid, corn starch, FDC yellow no. 6 aluminum lake, magnesium stearate, mannitol, pineapple flavor, povidone K30

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

you may also use this number to report serious adverse events associated with the use of this product

Children's Coltalin

NDC 51467-006-01

Acetaminophen - Pain Reliever-Fever Reducer
 Chlorpheniramine maleate - Antihistamine
 Phenylephrine hydrochloride- Decongestant

See new warnings information

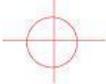
Sugar Free

Aspirin Free

24 Chewable Tablets

Safety Sealed

Do not use if individually sealed foil unit dose pouches are torn, broken, or shows the evidence of being opened.



DRUG FACTS	Active Ingredients (in each tablet)	Purpose
Acetaminophen 80 mg	-----	Pain reliever-fever reducer
Chlorpheniramine maleate 0.5 mg	-----	Antihistamine
Phenylephrine hydrochloride 1.25 mg	-----	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold, the flu, or hay fever:
 - sore throat
 - minor aches and pains
 - headache
 - itching of the nose or throat
 - runny nose
 - sneezing
 - itchy, watery eyes due to hay fever
 - sinus congestion and pressure
 - nasal congestion
- temporarily reduces fever
- promotes nasal and/or sinus drainage

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen

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.
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease)
- for 2 weeks after stopping a MAOI drug

Ask a doctor before use if your child has

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as chronic bronchitis

Ask a doctor or pharmacist before use if your child is

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

When using this product

- do not exceed recommended dosage
- may cause drowsiness (sedatives and tranquilizers may increase the drowsiness effect)
- may cause excitability especially in children

Stop use and ask a doctor if

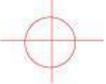
- sore throat persists for more than 2 days
- sore throat is severe
- sore throat is accompanied or followed by: fever
- headache
- rash
- nausea
- vomiting
- pain or nasal congestion gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- if nervousness, dizziness or sleeplessness occur

Do not give to children under 6 years of age unless directed by a doctor.

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 for children even if you do not notice any signs or symptoms.

Directions

Children 6 to under 12 years | Chew tablets before swallowing. 4 tablets every 4 hours while



藥品資料

有效成份(每片含量)	目的
對乙酰氨基酚 80 毫克	止痛退燒藥
馬來氯苯那敏 0.5 毫克	抗組織胺
苯腎上腺素 1.25 毫克	鼻血管收縮藥

用途

暫時緩解由感冒、流感和花粉熱引起的以下症狀：

- 喉嚨腫痛
- 輕微疼痛
- 頭痛
- 鼻子或喉嚨發癢
- 流鼻涕
- 打噴嚏
- 由花粉熱引起的眼癢、流淚
- 鼻竇充血和壓力
- 鼻塞

暫時退燒 改善鼻子和/或鼻竇的引流

警告

肝臟警告：本產品含有對乙酰氨基酚，可導致肝臟嚴重損傷，如果您的孩子：

- 在24小時內服用超過5片，這是本產品的最大日用量
- 與其他含有對乙酰氨基酚的藥物一起服用

不適用於

- 與其他含有對乙酰氨基酚的藥物（處方或非處方）一起使用。如果你不確定某種藥物是否含有對乙酰氨基酚，請向醫生或藥劑師諮詢。
- 如果孩子正在服用處方的單胺氧化酶抑制劑(MAOI)（用於治療抑鬱症、精神或情緒疾病或帕金森氏症的某些藥物）。在停止MAOI藥物後達兩周

在使用前向醫生諮詢，如果您的孩子有

- 肝臟疾病
- 心臟病
- 高血壓
- 甲狀腺疾病
- 糖尿病
- 青光眼
- 慢性支氣管炎等呼吸疾病

在使用前向醫生或藥劑師諮詢，如果孩子正在

- 服用血液稀釋藥物或凝膠
- 服用鎮靜藥或安定藥
- 服用處方藥物，而且不知道是否含有MAOI

在使用本產品時

- 切勿超過建議劑量
- 可能引起嗜睡（鎮靜藥或安定藥可增加嗜睡作用）。可能引起興奮性，特別是對於兒童

停止使用並向醫生諮詢，如果

- 咽喉疼痛持續超過2天
- 咽喉腫痛變嚴重
- 咽喉腫痛伴隨以下症狀：發燒、頭痛、皮疹、胸悶、嘔吐
- 疼痛或鼻塞變嚴重或持續超過5天
- 發燒變嚴重並持續超過3天
- 出現紅腫
- 出現新症狀
- 如果出現神經緊張、頭暈或失眠症狀

除非有勸導，切勿給6歲以下兒童服用。

放置在兒童取不到的地方。 如果服用過量，請立即諮詢醫院藥物控制中心。無論是對於成人或是對於兒童而言，迅速的醫療處理都是至關重要的，即使你沒有發現任何徵兆或症狀也是如此。

使用說明（本產品不包括供成人使用的說明或完整的廣告資訊）



Insert flap here
 摺回盒內

of age symptoms persist, not to exceed 5 doses (20 tablets) in 24 hours, or as directed by a doctor.

Children under 6 years of age consult a doctor.

Other Information

- Phenylephrine: contains Phenylephrine 4.2 mg per tablet
- protect from light • store between 15° to 30°C (59° to 86°F)
- keep in a dry place

Inactive Ingredients

Aspartame, citric acid, corn starch, FD&C yellow no.6 aluminum lake, magnesium stearate, mannitol, pineapple flavor, povidone K30

Questions or comments?

(888) 221-3496
M-F 9 am to 5 pm
you may also use this number to report serious adverse events associated with the use of this product

6歲以下兒童 請醫藥

其他資訊

- 苯丙醇胺症患者，每片包含苯丙醇胺4.2毫克
- 避光保存 • 在攝氏15至30度（華氏59至86度）內儲存 • 於乾燥處保存

藥性成分

阿斯巴甜、檸檬酸、玉米澱粉、FD&C黃色6號—鋁鹽基、硬脂酸鎂、甘露醇、鳳梨香精、和聚維酮K30。

問題或意見？

(888) 221-3496 週一至週五 上午9時至下午5時
您還可以使用該電話號碼報告與使用本產品有關的嚴重副作用。

CHILDREN'S FRUIT FLAVORED

COLTALIN®

ANTIHISTAMINE/NASAL DECONGESTANT/PAIN RELIEVER-FEVER REDUCER

Do not use if individually sealed foil unit dose pouches are torn, broken, or shows the evidence of being opened.

Manufactured by:
Fortune Pharmaceutical Co., Ltd. Hong Kong
幸福醫藥有限公司
www.fortunepharm.com
香港產品 Made in Hong Kong

FP-USA-1050

NDC 51467-006-01

SAFETY SEALED

CHILDREN'S

COLTALIN®

Fruit Flavor CHEWABLE COLD TABLETS

ACETAMINOPHEN - PAIN RELIEVER-FEVER REDUCER 止痛藥 - 退燒藥
CHLORPHENIRAMINE MALEATE - ANTIHISTAMINE 抗組胺藥
PHENYLEPHRINE HYDROCHLORIDE - NASAL DECONGESTANT 鼻血管收縮藥

兒童 **幸福傷風素**

Temporarily relieves these symptoms due to a cold, the flu, or hay fever:
sore throat • minor aches and pains • headache • runny nose
itching of the nose or throat • sneezing • itchy, watery eyes due to hay fever • sinus congestion and pressure • nasal congestion
Temporarily reduces fever • Promotes nasal and/or sinus drainage

暫時緩解由感冒、流感和花粉熱引起的以下症狀：
• 咽喉腫痛
• 輕微疼痛 • 頭痛 • 流鼻涕 • 鼻子或喉嚨發癢 • 打噴嚏
• 由花粉熱引起的眼睛發癢、流淚 • 鼻竇充血和壓力 • 鼻塞
• 暫時退燒 • 改善鼻子和/或鼻竇的引流

24 CHEWABLE TABLETS/咀嚼片
In Individually Sealed Strip 獨立鋁箔密封包裝

SUGAR FREE • ASPIRIN FREE See new warnings information 請見最新警告資訊

LOT EXP

RV-FA-FA-00

兒童 **幸福傷風素**

抗過敏/通鼻塞/止痛解熱劑

菓子味

如盒內獨立密封鋁箔片被撕裂，損壞或有跡象顯示曾被打開，請勿使用。

Distributed by:
美國蘇氏藥業有限公司
SOLSTICE MEDICINE COMPANY
215 West Ann Street,
Los Angeles, CA 90012
Toll Free: 1-888-221-3496
www.solsticemed.com

CMYK Pantone 805C 2X 2767C 123C Diecut

US CHILDREN'S COLTALIN1050 02-11-2010(00)

CHILDRENS COLTALIN

acetaminophen, chlorpheniramine maleate, phenylephrine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51467-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	0.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1.25 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
PINEAPPLE (UNII: 2A88ZO081O)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	12mm
Flavor	PINEAPPLE	Imprint Code	F;O;R;T;U;N;E
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-006-01	24 in 1 CARTON; Type 0: Not a Combination Product	03/01/2004	

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(51467-006)