

CHILDRENS COLTALIN- acetaminophen, chlorpheniramine maleate, phenylephrine hydrochloride tablet, chewable
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 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.

Insert flap here
摺回盒內

DRUG FACTS		藥品資料	
Active Ingredients (in each tablet)		有效成份(每片含量)	
Acetaminophen 80 mg	Pain reliever- fever reducer	對乙酰氨基酚 80 毫克	止痛退燒藥
Chlorpheniramine maleate 0.5 mg	Antihistamine	馬來酸氯苯那敏 0.5 毫克	抗組胺藥
Phenylephrine hydrochloride 1.25 mg	Nasal decongestant	不腎上腺素 1.25 毫克	鼻血管收縮藥
Purpose		目的	
Pain reliever- fever reducer		止痛退燒藥	
Antihistamine		抗組胺藥	
Nasal decongestant		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：			
<ul style="list-style-type: none"> • 喉痛 • 鼻塞 • 頭痛 • 鼻子或喉嚨發癢 • 流鼻涕 • 打噴嚏 • 由花粉熱引起的眼睛發癢、流淚 • 鼻塞 • 鼻充血和壓力 • 鼻塞 			
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：			
<ul style="list-style-type: none"> • 在24小時內服用超過5劑，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 			
不應用於			
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一些藥物），在停止MAOI藥物後達兩週			
在使用前向醫生諮詢，如果您的孩子有			
<ul style="list-style-type: none"> • 肝臟疾病 • 心臟病 • 貧血 • 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			
服用血液稀釋藥物如華法林、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			
<ul style="list-style-type: none"> • 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			
<ul style="list-style-type: none"> • 腹痛持續超過2天 • 腹痛變得嚴重 • 腹痛伴隨以下症狀：發燒、嘔吐、皮疹、惡心、嘔吐、疼痛或鼻塞嚴重或持續超過6天、發燒嚴重並持續超過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 			
除非有醫囑，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，請立即撥醫藥諮詢專線或聯絡毒物控制中心。無論是否對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。			
服用說明 （本產品不包供成人使用的說明或完整的警告資訊。）			
6至12歲以下兒童		在吞下前咀嚼藥片，每4小時服用4片，如症狀持續，24小時內不超過5劑（20片），或遵醫囑	
6歲以下兒童 遵醫囑			
其他資訊			
<ul style="list-style-type: none"> • 苯丙酮尿症患者，每片包含苯丙氨酸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—鉍鹽基、硬脂酸鎂、甘氨酸、羧基丙烯酸、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 你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

SAFETY SEALED

CHILDREN'S

COLTALIN®

FP-USA-1050

NDC 51467-006-01

COLTALIN

COLTALIN

COLTALIN

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 1: Convenience Kit of Co-Package	03/01/2004	

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(51467-006)

Revised: 11/2019

FORTUNE PHARMACAL COMPANY LIMITED