

SPRINSOL- chlorpheniramine maleate 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)
Chlorpheniramine maleate 4 mg

Purpose
Antihistamine

Uses
temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
sneezing
runny nose
itching of the nose or throat
itchy, watery eyes

Warnings
Ask a doctor before use if you have
a breathing problem such as emphysema or chronic bronchitis
glaucoma
difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are
taking sedatives or tranquilizers

When using this product
do not exceed recommended dosage unless directed by a physician
may cause excitability especially in children
use caution when driving or operating machinery
avoid alcoholic beverages
may cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect

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

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

Other information

keep tightly sealed

protect from light

store between 20 to 25 C (68 to 77 F)

Inactive ingredients

colloidal silicon dioxide, corn starch, FD C red no. 40 aluminum lake, lactose monohydrate, 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

Sprinsol

Safely Sealed

NDC 51467-101-02

Chlorpheniramine maleate - Antihistamine

temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:

sneezing

runny nose

itching of the nose or throat

itchy, watery eyes

36 Tablets

In Individually Sealed Strip

Respiratory Series

Drug Facts
Active ingredient (in each tablet) Chlorpheniramine maleate 4 mg. **Purpose** Antihistamine

Uses
• Temporarily relieve these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
• sneezing • runny nose • itching of the nose or throat
• itchy, watery eyes

Warnings
Ask a doctor before use if you have:
• a swelling problem such as emphysema or chronic bronchitis • glaucoma
• difficulty in urination due to enlargement of the prostate gland
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
• do not exceed recommended dosage unless directed by a physician
• may cause excitability especially in children
• use cautiously when driving or operating machinery
• avoid alcoholic beverages
• may cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect

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children under 12 years of age: consult a doctor

Other information
• keep tightly sealed • protect from light • store between 20 to 25°C (68 to 77°F)

Inactive ingredients croscellose, silicon dioxide, corn starch, FD&C red #40, aluminum lake, lactose monohydrate, magnesium stearate, polyethylene glycol 400, sodium starch glycolate

Questions or comments? Call 1-800-368-6677 • ask us to print • you may also report serious side effects to this phone number.

藥品資料
有效成份 (每片含量) 馬來酸氯苯那敏 4 毫克 **主治** 抗組織胺

用途
• 暫時舒緩由花粉熱(過敏性鼻炎)或其他上呼吸系統引起的以下症狀:
• 打噴嚏 • 流鼻涕 • 鼻子或喉嚨發癢 • 眼睛發癢和淚眼

警告
在使用前請向醫生諮詢, 如果您有:
• 肺氣腫或慢性支氣管炎等呼吸問題 • 青光眼
• 因前列腺肥大引起的排尿困難
在使用前請向醫生或藥劑師諮詢, 如果您正在服用鎮靜劑或安眠藥

在服用本品時
• 勿超過建議劑量
• 可能引起興奮, 尤其是小孩
• 駕駛汽車或操作機械時要格外小心
• 避免飲酒或酒精飲品
• 可能引起嗜睡, 酒精、鎮靜劑或安眠藥可能會加重嗜睡

如果您懷孕正在哺乳, 請在服用前向醫藥專業人員查詢的, 並置在兒童拿不到的地方。如果服用過量, 請立即與醫藥專業人員聯絡。

使用說明
成人及 12 歲或以上: 每 4 至 6 小時服用 1 片, 24 小時內不可服用超過 6 片 (24 毫克), 或遵醫囑
12 歲以下兒童: 遵醫囑

其他資訊
• 密封保存 • 避光保存
• 在攝氏 20 至 25 度 (華氏 68 至 77 度) 內儲存

非活性成分 纖維素、玉米澱粉、FD&C 紅色 40 號湖藍、乳糖、聚乙二醇 400、羧基澱粉交聯鈉

問題或查詢? 請電 1-800-368-6677 或親臨 1-800-368-6677 查詢 • 亦可向美國此藥通報副作用的部門查詢

SPRINSOL Do not use if individual sealed foil unit dose pouches are torn, broken, or show evidence of being opened. Antihistamine Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Manufactured by: Fortune Pharmaceutical Co., Ltd. 製造商: 幸福過敏有限公司
www.fortunepharm.com • Made in Hong Kong 香港製造

幸福過敏素
SPRINSOL

SAFELY SEALED NDC 51467-101-02

SPRINSOL

Chlorpheniramine Maleate - Antihistamine
馬來酸氯苯那敏 - 抗組織胺

幸福過敏素

• Temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
• sneezing • runny nose • itching of the nose or throat
• itchy, watery eyes

• 暫時舒緩由花粉熱(過敏性鼻炎)或其他上呼吸系統引起的以下症狀:
• 打噴嚏 • 流鼻涕 • 鼻子或喉嚨發癢
• 眼睛發癢和淚眼

36 TABLETS/片
In Individually Sealed Pouches 獨立包裝箔包裝

幸福過敏素
SPRINSOL

幸福過敏素 抗組織胺

如盒內獨立密封箔片裝藥劑, 藥劑或有時會顯示包裝打開, 請勿使用。保存外盒以查詢完整的醫藥和產品資訊。

Distributed by: 美國福大藥業有限公司
8400 Wilshire Boulevard, Suite 200
Los Angeles, CA 90048 U.S.A.
Tel: (310) 201-2000 Fax: (310) 201-2000

SPRINSOL

chlorpheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51467-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	FORTUNE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-101-01	2 in 1 BOX	09/22/2017	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-101-02	3 in 1 BOX	09/22/2017	
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	09/22/2017	

Labeler - FORTUNE PHARMACAL COMPANY LIMITED (686280561)

Establishment

Name	Address	ID/FEI	Business Operations
FORTUNE PHARMACAL COMPANY LIMITED		686280561	manufacture(51467-101)

