

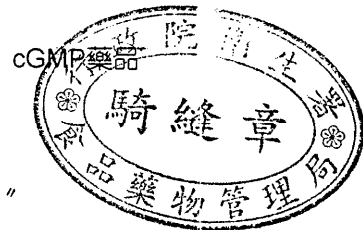
# 外盒、仿單、標籤粘貼表

產品名稱	“杏輝”喘必定錠	申請廠商	杏輝藥品工業股份有限公司
衛生署給證號碼	衛署藥製	字第	045733 號 G-8058 號

“杏輝”

## 喘必定 錠

### ASMATIN Tablets “Sinphar”



99.7.12

本製劑用來治療及預防支氣管氣喘和支氣管痙攣，可以解除各種型式的支氣管痙攣及對各種引起支氣管收縮的刺激，對於支氣管肌肉因具有快速的起始作用及很長的作用時間，故療效顯著。縱使長期使用，其耐受性非常優異。

成分：Each Tablet contains：

Fenoterol HBr.....2.5mg

賦形劑：Microcrystalline cellulose、Talc、Magnesium stearate、Colloidal silicon dioxide、Lactose

適應症：下列支氣管痙攣疾患之預防與治療：

支氣管氣喘、阻塞性支氣管炎、慢性支氣管炎、氣腫和伴有支氣管痙攣之肺支氣管障礙。

用法用量：治療期間必須在醫師的觀察下，劑量可按病人個別反應和疾病的嚴重性來增減。

一般建議劑量如下：（應該在飯前服用）

成人：每天3次，每次1~2錠。

學童（6-14歲）：每天3次，每次1錠。

小孩（1-6歲）：每天3次，每次1/2~1錠。

禁忌症：甲狀腺機能亢進症，癰腫下主動脈狹窄，心跳過快之心律不整。

藥物交互作用：

1.β-腎上腺素，抗副交感神經劑和黃鹼(Xanthine)的衍生物可能會加強本劑作用。

2.β接受體阻斷劑具有拮抗的作用。

注意事項：

1.只有在醫師的監督下才可以與其他變交感神經性支氣管擴張劑併用。

2.孕婦使用本藥亦須注意慣例的注意事項，本藥對於子宮收縮劑具有抑制作用，必須列入考慮。

3.目前若正使用或最近使用MAO抑制劑時，必須特別謹慎。

4.對於患有不穩定糖尿病患者，應小心使用本藥。

5.本藥若用於患者最近有心肌梗塞及嚴重心臟或血管障礙，尤其使用超過推薦劑量時，必須在醫師指示下才可以使用。

6.如治療不能產生預期效果時，必須尋求醫師的指示，以決定新的治療計劃。

7.小孩應在醫師的指示與成人的監督之下才可服用本藥。

副作用：

1.本藥的耐受性良好，但偶爾會有輕微的手指震顫、不安或心悸發生。

2.本藥偶有眩暈、疲勞、頭痛、出汗、口乾、心室障礙或心絞痛，若有此現象發生即應減低劑量。

3.若服用過量時會有以下列症狀發生：潮紅、手指震顫、噁心、心跳過快、心縮壓增加、心舒壓降低、焦慮、興奮和可能發生期外收縮。

本藥須由醫師處方使用

衛署藥製字第045733號  
G-8058號

包裝：6-1000粒鋁箔盒裝、塑膠瓶裝。

貯藏：請存放於25℃以下、陰涼及兒童伸手不及之處所。

cGMP



® 杏輝藥品工業股份有限公司

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※ 外文仿單應檢附中文譯文

產品名稱

衛生署給證

分有限公司

-8058 號



99.7.12

## ASMATIN Tablets "Sinphar"

Fenoterol hydrobromide is a direct acting sympathomimetic agent, selectively stimulating beta<sub>2</sub>-receptors in the therapeutic dose range. Fenoterol relaxes bronchial and vascular smooth muscle and protects against bronchoconstricting stimulus such as histamine, methacholine, cold air, and allergen (early response). In clinical studies fenoterol was shown to be highly efficacious in manifest bronchospasm. It prevents bronchoconstriction following exposure to various stimulus such as exercise, cold air, and the early response following allergen exposure.

Active ingredient: Each tablet contains:

Fenoterol HBr.....2.5mg

Excipients:

Microcrystalline cellulose, Talc, Magnesium stearate, Colloidal silicon dioxide, Lactose

Indications:

For the prophylaxis and treatment of bronchospasm in bronchial asthma, obstructive bronchitis, chronic bronchitis, emphysema and broncho-pulmonary disorders with bronchospasm.

Dosage and Administration:

Under doctor's supervision, the dosage can be adjusted according to the illness. Generally recommended as follows: (Take before meals)

Adults: 3 times a day, 1~2 Tablets per dose.

Children (6-14 years old): 3 times a day, 1 tablet per dose.

Children (1-6 years old): 3 times a day, 1/2-1 tablet per dose.

Contraindications:

Hypertrophic obstructive cardiomyopathy, tachyarrhythmia.

Drug interactions:

1. Beta-adrenergics, anticholinergics, and xanthine derivatives (such as theophylline) may enhance the effect of fenoterol. The concurrent administration of other beta<sub>2</sub>-agonists, systemically available anticholinergics and xanthine derivatives (e.g. Theophylline) may increase the side effects.

2. A potentially serious reduction in bronchodilatation may occur during concurrent administration of beta-blockers.

Special precautions:

1. Other sympathomimetic bronchodilators should only be used with Fenoterol hydrobromide under medical supervision.

2. Pre-clinical data, have shown no evidence of ill-effects in pregnancy. Nonetheless, especially during the first trimester, should be exercised. The inhibitory effect of fenoterol on uterine contraction should be taken into account.

3. Beta-adrenergic agonists should be administered with caution to patients being treated with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants, since the action of beta adrenergic agonists may be enhanced.

4. Care should be taken for patients with unstable diabetic control.

5. In the following conditions Fenoterol hydrobromide should only be used after careful risk/benefit assessment, especially when doses higher than recommended are used: insufficiently controlled diabetes mellitus, recent myocardial infarction, severe organic heart or vascular disorders, hyperthyroidism, pheochromocytoma.

6. The use of increasing amounts of beta<sub>2</sub>-agonist containing products on a regular basis to control symptoms of bronchial obstruction may suggest declining disease control. In the case of acute, rapidly worsening dyspnea (difficulty in breathing) a doctor should be consulted immediately.

7. Children should be directed by doctor and adults before use.

Side Effects:

1. Potentially serious hypokalemia may result from beta<sub>2</sub>-agonist therapy. As with cough, local irritation and less common, paradoxical bronchoconstriction have been reported.

2. Frequent undesirable effects of Fenoterol hydrobromide are fine tremor of skeletal muscles and nervousness, headache, dizziness, tachycardia and palpitations.

3. As with other beta-mimetics, nausea, vomiting, sweating, weakness and myalgia/muscle cramps may occur.



SINPHAR PHARMACEUTICAL CO., LTD.

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