

Fluconazol cinfa 150 mg capsules

Read all of this leaflet carefully before you start taking this medicine, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fluconazol cinfa is and what it is used for.
2. What you need to know before taking Fluconazol cinfa.
3. How to take Fluconazol cinfa.
4. Possible side effects.
5. How to store Fluconazol cinfa.
6. Contents of the pack and other information.

1. What Fluconazol cinfa is and what it is used for

Fluconazol cinfa belongs to a group of medicines called “antifungals”. The active agent is fluconazole.

Fluconazol cinfa is used to treat infections caused by fungi and may also be used to stop you from getting a *Candida* infection. The most common cause of fungal infection is a yeast called *Candida*.

Adults

You might be given this medicine by your doctor to treat the following types of fungal infection:

- Cryptococcal meningitis – a fungal infection in the brain.
- Coccidioidomycosis – a disease of the bronchopulmonary system.
- Infections caused by *Candida* found in the blood stream, body organs (e.g. heart, lungs) or urinary tract.
- Mucosal candidiasis – an infection affecting the lining of the mouth, throat or linked to the use of dentures.
- Genital candidiasis – infection of the vagina or penis.
- Skin infections – e.g. athlete’s foot, ringworm, jock itch, nail infection.

You might also be prescribed fluconazol to:

- Stop cryptococcal meningitis from coming back.
- Stop mucosal infections due to *Candida* from coming back.
- Reduce the repeated occurrence of vaginal infections due to *Candida*.
- Prevent the spread of infections caused by *Candida* (if your immune system is weak and not working properly).

Children and adolescents (aged 0 to 17 years)

You might be given this medicine by your doctor to treat the following types of fungal infection:

- Mucosal candidiasis – infection affecting the lining of the mouth or throat.
- Infections caused by *Candida* found in the blood stream, body organs (e.g. heart, lungs) or urinary tract.
- Cryptococcal meningitis – a fungal infection in the brain.

You might also be prescribed Fluconazol cinfa to:

- Prevent the spread of infections caused by *Candida* (if your immune system is weak and not working properly).

Stop cryptococcal meningitis from coming back.

2. What you need to know before you take Fluconazol cinfa

Do not take Fluconazol cinfa

- If you are allergic to Fluconazole, other medicines you have taken to treat fungal infections or any of the other ingredients of this medicine (listed in section 6). The symptoms may include itching, reddening of the skin or breathlessness.
- If you are taking astemizole or terfenadine (antihistamines for allergies).
- If you are taking cisapride (used for stomach upsets).
- If you are taking pimozide (used for treating mental illness).
- If you are taking quinidine (used for treating heart arrhythmia).
- If you are taking erythromycin (an antibiotic for treating infections).

Warnings and precautions

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- If you have liver or kidney problems.
- If you are suffering from heart disease, including heart rhythm problems.
- If you have abnormal levels of potassium, calcium or magnesium in the blood.
- If severe skin reactions develop (itching, reddening of the skin or breathlessness).
- If signs of “adrenal insufficiency” appear, in which the adrenal glands do not produce a sufficient amount of certain hormones, such as cortisol (chronic or prolonged fatigue, muscle weakness, appetiteless, weight loss, abdominal pain).
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Fluconazole.
- The fungal infection does not improve, as alternative antifungal therapy may be needed.

Serious skin reaction including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Fluconazole. Stop taking Fluconazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Fluconazol cinfa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies), cisapride (used for stomach upsets) or pimozide (used for treating mental illness), quinidine (used for treating heart arrhythmia), erythromycin (an antibiotic for treating infections), since these medicines should not be taken with Fluconazol cinfa (see section: “Do not take Fluconazol cinfa”).

There are some medicines that may interact with Fluconazole. Make sure your doctor knows if you are taking any of the following medicines:

- Rifampicin or rifabutin (antibiotics for infections).
- Alfentanil, fentanyl (used as anaesthetics).
- Amitriptyline, nortriptyline (used as anti-depressants).
- Amphotericin B, voriconazole (anti-fungals).
- Medicines that thin the blood to prevent blood clots (warfarin or other similar medicines).
- Benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety.
- Carbamazepine, phenytoin (used for treating seizures).
- Nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for hypertension - high blood pressure).
- Olaparib (used to treat ovarian cancer).
- Cyclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection).
- Cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer.
- Halofantrine (medicine to treat malaria).
- Statins (atorvastatin, simvastatin and Fluvastatin or similar medicines) used for reducing high cholesterol levels.
- Methadone (used for pain).
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs –NSAIDs–).
- Oral contraceptives.
- Prednisolone (steroid).
- Zidovudine, also known as AZT; saquinavir (used in HIV-infected patients).
- Medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline (used to control asthma).
- Tofacitinib (used to treat rheumatoid arthritis).
- Tolvaptan (used to treat hyponatremia [low blood sodium levels] or to slow the deterioration of kidney function).
- Vitamin A (nutritional supplement).
- Ivacaftor (used to treat cystic fibrosis).
- Amiodarone (used to treat an irregular heartbeat “arrhythmia”).
- Hydrochlorothiazide (diuretic).
- Irutinib (used to treat blood cancer).

Fluconazol cinfa with food and drink

You can take the medicine with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are planning to become pregnant, it is recommended that you wait until one week after a single dose of fluconazole before trying to fall pregnant.

For longer courses of fluconazole treatment, talk to your doctor about the need to use adequate contraception during treatment, the use of which should be maintained for one week after the last dose.

Do not take fluconazole if you are pregnant, think you may be pregnant or are planning to have a baby or breast-feeding, unless your doctor tells you to.

If you become pregnant while taking this medicine or within one week after the most recent dose, talk to your doctor.

You can continue breast-feeding after taking a single dose of 150 mg of fluconazole. Stop breast-feeding if you are taking repeated doses of fluconazole.

Fluconazole taken during the first trimester or second of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the heart, the bones and/or muscles.

Cases of babies born with congenital abnormalities affecting the skull, ears and thigh and elbow bones have been reported in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The relationship between fluconazole and these cases is not clear.

Driving and using machines

When driving or operating machines, you should keep in mind that dizziness or seizures may occasionally occur.

Fluconazol cinfa contains lactose.

If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

Fluconazol cinfa contains sodium.

This medicine contains less than 1 mmol (23 mg) of sodium per capsule; it is essentially “sodium-free”.

3. How to take Fluconazol cinfa

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist again if you are not sure.

The capsules should be swallowed whole with a glass of water. It is best to take your medicines at the same time each day.

The usual recommended doses of this medicine for different infections are listed below:

Adults

Condition	Dose
To treat cryptococcal meningitis	400 mg on the first day then 200 mg to 400 mg once a day for 6 to 8 weeks or longer if needed. Sometimes the dose is increased up to 800 mg
To stop cryptococcal meningitis from coming back	200 mg once a day until your doctor tells you
To treat coccidioidomycosis	200 mg to 400 mg once a day from 11 months to 24 months or longer if needed. Sometimes the dose is increased up to 800 mg
To treat internal fungal infections caused by <i>Candida</i>	800 mg on the first day then 400 mg once a day until your doctor tells you
To treat mucosal infections affecting the lining of the mouth, throat or linked to the use of dentures	200 mg to 400 mg on the first day and then 100 mg to 200 mg once a day until your doctor tells you

治療口腔，咽喉黏膜或與假牙相關的感染	第一日 200 毫克到 400 毫克，然後每日 100 毫克到 200 毫克，直到你的醫生告訴你療程結束為止。
治療黏膜念珠菌病，劑量取決於感染部位	每日一次 50 毫克到 400 毫克，持續 7 到 30 天，直到你的醫生告訴你療程結束為止。
防止口腔和咽喉黏膜內的感染	每日一次 100 毫克到 200 毫克，或每星期三次每次 200 毫克，如感染的風險仍然持續。
治療生殖器念珠菌病	單次劑量 150 毫克。
減少重複發生的陰道念珠菌病	每 3 日一次每次 150 毫克最多 3 次(即第 1，第 4 同第 7 日)，然後每星期一次，如感染的風險仍然持續。
治療皮膚或指甲的真菌感染	取決於感染部位，每日一次 50 毫克，每星期一次 150 毫克，每星期一次 300 至 400 毫克，持續 1 至 4 星期(香港腳可能需要長達 6 星期的時間，繼續治療指甲感染，直到健康指甲長出)。
以防止由念珠菌引起的感染擴散(如果你的免疫系統很弱並且運作不正常)	每日一次 200 毫克到 400 毫克，如感染的風險仍然持續。

青少年:12至17歲
請遵照醫生處方的劑量(成人或兒童劑量)

11歲或以下之兒童

兒童的最高劑量為每日 400 毫克。
劑量根據你孩子的體重（千克）計算。

狀況	每日劑量
由念珠菌引起的黏膜念珠菌病和咽喉感染：治療的劑量和療程時間取決於感染的嚴重程度及其位置	每公斤體重服用 3 毫克(第 1 日可每公斤體重服用 6 毫克)。
隱球菌性腦膜炎或由念珠菌引起的內部真菌感染	天每公斤體重服用 6 毫克至 12 毫克每
阻止隱球菌性腦膜炎的復發	每天每公斤體重服用 6 毫克
以防止孩子感染念珠菌引起的感染(如果他們的免疫系統運作不正常)	每天每公斤體重服用 3 毫克至 12 毫克

用於0-4星期大之兒童

用於 3 至 4 星期大之兒童：
- 根據上表中建議的劑量，但每 2 天用藥一次。每千克體重每 48 小時最高劑量為 12 毫克。

用於少於 2 星期大之兒童：
- 與上表中建議使用相同的劑量，但每 3 天用藥一次。每千克體重每 72 小時最高劑量為 12 毫克。

長者

可使用成人劑量，除非患有腎臟問題。

患有腎臟問題的病人

你的醫生可能會改變劑量，這取決於你的腎臟的功能。

假如使用莎華 -「婦康健」多於你應使用份量

一次過服用過量的藥物會讓你感覺不適。如果過量或意外服用，請立即告知你的醫生或藥劑師，並註明藥物和服用份量。

服用過量藥物的症狀可能包括聽覺、視覺、感覺和思考不真實的事物（幻覺和偏執行為）。開始對症治療可能是適當的（如有必要，可採用支持性措施）。我們建議將藥物說明書和包裝交給醫療服務提供方。

假如你忘記使用莎華 -「婦康健」

請勿服用雙倍劑量來彌補忘記的劑量。如果你忘記服用，當記起時盡快服用。如果已接近下一次服藥的時間，請不要服用錯過的劑量並等待服用下一劑。

如果你對使用此藥有任何疑問，請諮詢你的醫生或藥劑師。

4. 可能的副作用

像其他藥物一樣，此藥物可能會引起副作用，儘管並不是所有人都會有此情況。

有些人會出現過敏反應，然而嚴重的過敏反應很少見。如果出現副作用，請立即通知醫生或藥劑師。這包括本說明書中未列出的副作用。

如果你出現以下任何症狀，請停止服用氟康唑並立即就醫。

- 呼吸時突然喘息，呼吸急促或胸腔收窄
- 眼瞼、面部或嘴唇腫脹
- 全身發癢，皮膚發紅或出現痕癢的紅色斑點
- 皮疹
- 嚴重的皮膚反應如皮疹引起水泡(這可能會影響口腔和舌頭)
- 廣泛的皮疹，體溫高和淋巴結腫大 (DRESS綜合徵或藥物過敏綜合徵)
- 莎華 -「婦康健」會影響肝臟。可能的肝臟問題症狀包括：
- 疲勞
- 食欲不振
- 嘔吐
- 皮膚或眼白部份變黃(黃疸)

如果出現任何這些症狀，請立即停止服用莎華 -「婦康健」並通知醫生。

其他副作用

如果你認為自己的副作用嚴重，或者你發現本說明書中沒有列出的任何其他副作用，請告訴你的醫生或藥劑師。

常見的副作用，每 10 名患者中有 1 人可能會受影響：

- 頭痛
- 胃部不適，腹瀉，噁心，嘔吐
- 血液分析結果，肝功能指數偏高
- 皮疹

不常見的副作用，每 100 名患者中有 1 人可能會受影響：

- 紅血細胞減少，使你的皮膚變得蒼白，導致虛弱和呼吸困難
- 減少食慾
- 無法入睡，麻木
- 抽搐，頭暈，刺痛，針刺的感覺，刺痛或麻木，味覺轉變。
- 便秘，消化不良，脹氣，口乾
- 肌肉疼痛
- 肝臟受損及皮膚和眼睛發黃(黃疸)
- 皮疹，水泡(蕁疹)，痕癢，出汗增多
- 疲倦，感覺不適，發燒

罕見的副作用，每 1,000 名患者中有 1 人可能會受影響：

- 白血球細胞數量低於正常值，抵抗感染和出血的能力下降。
- 皮膚偏紅或偏向紫色。這可能是由於血小板數量少或血細胞的其他變化。
- 血液中的變化(高水平的膽固醇，脂肪)
- 血鈣水平低
- 震顫
- 心電圖異常 (ECG)，心跳或心律出現變化
- 肝衰竭
- 過敏反應(有時會很嚴重)，包括擴散的皮疹和水泡，脫皮，嚴重的過敏反應，面部或嘴唇腫脹
- 脫髮

未知頻率（無法從可用數據中估算）：

- 與皮疹，發熱，腺體發炎，白細胞類型增多（嗜酸性粒細胞增多）和內部器官（肝，肺，心臟，腎臟和大腸）發炎的過敏反應（對藥物的反應或與嗜酸性粒細胞增多和皮疹的反應）全身症狀(DRESS)。

報告出現的副作用

如果你出現任何副作用，請諮詢你的醫生或藥劑師，即使本說明書中未列出的可能副作用。

通過報告副作用，你可以幫助提供更多有關此藥安全性的信息。

5. 如何貯存莎華 -「婦康健」

請將藥物存放於兒童不能觸及和視線範圍以外。
在標籤和紙盒上註明的有效期後（月/年）切勿使用，有效期所指的是該月的最後一日。

請勿貯存於攝氏 25 度以上。

請勿丟棄任何藥物於污水及家居垃圾中，請向你的藥劑師查詢如何棄置不再使用的藥物，這項措施有助保護環境。

6. 包裝及其他資料

莎華 -「婦康健」包含什麼：

- 主要成份是氟康唑 (fluconazole)。每粒含有 150 毫克氟康唑 (fluconazole)。
- 其他成份包括：
- 藥丸內部成份: Pregelatinized maize starch, sodium carboxymethyl (type A) (from potato), magnesium stearate, anhydrous colloidal silica, lactose monohydrate (lactose) and sodium lauryl sulphate.
- 藥丸外部成份: Gelatin, titanium dioxide (E171), indigo carmine (E132), quinoline yellow (E104) and erythrosine (E-127).

產品外觀和包裝內容

膠囊是橙黃色和果色

每盒裝有 1 粒。

製造商及營銷持有人
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To treat mucosal candidiasis the dose depends on where the infection is located	50 mg to 400 mg once a day for 7 to 30 days until your doctor tells you
To prevent recurrence of mucosal infections that affect the lining of the mouth and throat	100 mg to 200 mg once a day, or 200 mg 3 times a week, while you are at risk of developing an infection
To treat genital candidiasis	150 mg as a single dose
To reduce recurrence of genital candidiasis	150 mg every three days for a total of 3 doses (day 1, 4, and 7) and then once a week while the risk of developing an infection continues
To treat fungal infections of the skin or nails	Depending on the site of the infection 50 mg once a day, 150 mg once a week, 300 to 400 mg once a week for 1 to 4 weeks (up to 6 weeks may be needed for athlete's foot, for nail infection treatment until a healthy nail grows)
To prevent the spread of infections caused by <i>Candida</i> (if your immune system is weak and not working properly)	200 mg to 400 mg once a day while you are at risk of developing an infection

Use in children aged 12 to 17 years:
Follow the dose prescribed by your doctor (either adult or children dosage).

Use in children up to 11 years of age
The maximum dose for children is 400 mg a day.

The dose will be based on the child's weight in kilograms.

Condition	Daily Dose
Mucosal candidiasis and throat infections caused by <i>Candida</i> – the dose and duration of treatment depend on the severity of the infection and where the infection is located	3 mg per kg of body weight once a day (6 mg per kg of body weight can be given on the first day)
Cryptococcal meningitis or internal fungal infections caused by <i>Candida</i>	6 mg to 12 mg per kg of body weight once a day
To stop cryptococcal meningitis from coming back	6 mg per kg of body weight once a day
To prevent the child from developing an infection caused by <i>Candida</i> (if their immune system is weak and not working properly)	3 mg to 12 mg per kg of body weight once daily

Use in children aged 0 to 4 weeks

Use in children aged 3 to 4 weeks:
- The same dose as described above but given once every 2 days. The maximum dose is 12 mg per kg of body weight every 48 hours.

Use in children less than 2 weeks old:
- The same dose as described above but given once every 3 days. The maximum dose is 12 mg per kg of body weight every 72 hours.

Elderly patients

The usual adult dose should be given unless you have kidney problems.

Patients with kidney problems

Your doctor may modify your dose, depending on your kidney function.

If you take more Fluconazol cinfa that you should

Taking too many capsules at once may make you unwell. In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). It may be appropriate to initiate symptomatic treatment (with supportive measures and gastric lavage if necessary) We recommend taking the medicine leaflet and package to the healthcare provider.

If you forget to take Fluconazol cinfa:

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

If you have any further questions on using this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some people develop allergic reactions although serious allergic reactions are rare. If you get a side effect, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet.

Stop taking Fluconazole and seek medical attention immediately if you get any of the following symptoms.

- Sudden wheezing, breathlessness or tightness in the chest.
- Swelling of the eyelids, face or lips.
- Itching all over the body, reddening of the skin or itchy red spots.
- Skin rash.
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Fluconazole may affect your liver. The signs of liver problems include:

- Fatigue.
- Loss of appetite.
- Vomiting.
- Yellowing of the skin or the whites of the eyes (jaundice).

If any of these symptoms occur, stop taking fluconazole and **tell your doctor immediately**.

Other side effects:

Additionally, if any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common side effects (may affect up to 1 in 10 patients):

- Headache.
- Stomachache, diarrhoea, feeling sick, vomiting.
- High results of blood tests indicative of liver function.
- Skin rash.

Uncommon side effects (may affect up to 1 in 100 patients):

- Reduction in red blood cells which can make skin pale and cause weakness or breathlessness.
- Loss of appetite.
- Inability to sleep, feeling drowsy.
- Seizures, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste.
- Constipation, difficult digestion, wind, dry mouth.
- Aching muscles.
- Liver damage and yellowing of the skin and eyes (jaundice).
- Wheals, blistering (hives), itching, increased sweating.
- Tiredness, general feeling of being unwell, fever.

Rare side effects (may affect up to 1 in 1,000 patients):

- Lower than normal white blood cells that help defend us against infections and blood cells that help to stop bleeding.
- Red or purple discolouration of the skin, which may be caused by a low platelet count, other blood cell changes.
- Changes in blood tests (high levels of cholesterol, fats).
- Low levels of potassium in the blood.
- Tremor.
- Abnormal electrocardiogram (ECG), changes in the heart rate or rhythm.
- Liver failure.
- Allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe allergic reactions, swelling of the lips or face.
- Hair loss.

Unknown frequency (cannot be estimated from the available data):

- Hypersensitivity reaction with skin rash, fever, inflamed glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (reaction to the medicine or rash with eosinophilia and systemic symptoms [DRESS]).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluconazol cinfa

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

Do not store at a temperature above 25°C.

Do not dispose of any medicines via waste water or household waste. If unsure, ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fluconazol cinfa contains

- The active agent is fluconazole. Each hard capsule contains 150 mg of fluconazole.

- The other ingredients (excipients) are:

Capsule ingredients: pregelatinized maize starch, sodium carboxymethyl (type A) (from potato), magnesium stearate, colloidal anhydrous silica, lactose monohydrate (lactose), and sodium lauryl sulphate.

Composition of the capsule: gelatine, titanium dioxide (E-171), indigotin (E-132), quinoline yellow (E104), and erythrosine (E-127).

What the product looks like and contents of the pack

The capsules have a yellow-orange body and a maroon cap.

It is provided in packs of 1 capsule.

Marketing authorisation holder and manufacturer

Laboratorios Cinfa, SA
C/ Olaz-Chipi, 10. Polígono Industrial Areta.
31620 Huarte (Navarre) - Spain

Distributor

Reich Pharm Limited
Unit 3001, 30/F, Citicorp Centre, 18 Whitfield Road, Hong Kong
Tel.: 2470 1927 Fax.: 2470 3448

HK Reg. No. 58373

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說明書：使用者說明

莎華 -「婦康健」150毫克

此說明書含有重要資訊。使用此藥物前請細心閱讀此說明書全部內容。

- 請保留此說明書，以便可以再次翻閱。
- 如有任何問題，請向你的醫生或藥劑師查詢。
- 此藥只處方給你，請勿給其他人使用，即使對方病徵跟你相似也可能造成傷害。
- 如有任何副作用，請咨詢醫生或藥劑師，此包括任何未在此說明書列出的任何可能的副作用。請參閱第 4 節

這張說明書內包含甚麼資料？

- 莎華 -「婦康健」，是甚麼及用於甚麼情況
- 使用莎華 -「婦康健」，前你需要留意甚麼
- 如何使用莎華 -「婦康健」
- 可能的副作用
- 如何貯存莎華 -「婦康健」
- 包裝及其他資料

1. 莎華 -「婦康健」是甚麼及用於甚麼情況

莎華 -「婦康健」屬於一種“抗真菌菌”的藥物，其主要成份為氟康唑 (fluconazole)。

莎華 -「婦康健」用於治療由真菌引起的感染，也可用於阻止感染念珠菌。真菌感染最 常見原因是一種叫做念珠菌的酵母。

成人

你的醫生可能會給你這種藥物來治療下列類型的真菌感染：

- 隱球菌性腦膜炎 - 大腦的真菌感染。
- 球孢子菌病 - 支氣管疾病。
- 在血液，身體器官(如：心或肺或尿道中的)局部念珠菌感染。
- 黏膜念珠菌病 - 口腔，喉嚨或與假牙相關的感染。
- 生殖器念珠菌病 - 陰道或陰莖的感染
- 皮膚感染 - 足皸(香港腳)，頭癬，股癬，指甲感染。

氟康唑亦用作處方於：

- 防止隱球菌性腦膜炎的復發。
- 防止黏膜感染的復發。
- 減少念珠菌感染的重複發生。
- 防止由念珠菌引起的感染擴散(如果你的免疫系統很弱並且運作不正常)。

兒童和青少年 (0- 17歲)

你的醫生可能會給你這種藥物來治療下列類型的真菌感染：

- 黏膜念珠菌病 - 口腔，喉嚨的感染
- 在血液，身體器官(如：心或肺或尿道中的)局部念珠菌感染。
- 隱球菌性腦膜炎 - 大腦的真菌感染。

莎華 -「婦康健」也可以處方用作：

- 防止由念珠菌引起的感染擴散(如果你的免疫系統很弱並且運作不正常)。
- 防止隱球菌性腦膜炎的復發。

2. 使用莎華 -「婦康健」前你需要留意甚麼？

請勿使用莎華 -「婦康健」：

- 如你對氟康唑 (fluconazole) 或莎華 -「婦康健」中的任何其他成分或用於治療真菌感染的任何其他藥物過敏。症狀可能包括痕癢，皮膚發紅或呼吸困難。
- 如你服用阿司咪唑或特非那定(抗組織胺藥物治療過敏)。
- 如你服用西沙必利(用於治療胃部不適)。
- 如你服用匹莫齊特(用於治療精神疾病)。
- 如你服用奎尼丁(用於治療心律不正)。
- 如你服用紅霉素(一種治療感染的抗生素)。

警告和注意事項

服用莎華 -「婦康健」之前先諮詢你的醫生或藥劑師

- 如你有肝臟或腎臟問題。
- 如你患有心臟病，包括心律問題。
- 如你血液中的鉀，鈣或鎂含量不正常。
- 如你出現嚴重的皮膚反應(痕癢，皮膚發紅或呼吸困難)。
- 如果出現「腎上腺功能不全」的跡象，表明腎上腺不能產生足夠量的某些激素，例如皮質醇（慢性或長期疲勞，肌肉無力，食慾不振，體重減輕，腹痛）。
- 服用氟康唑後，如果曾經出現嚴重的皮疹或皮膚脫皮，起水疱和或口瘡。
- 真菌感染情況並沒有改善，可能需要其他抗真菌治療。

與氟康唑有關的嚴重皮膚反應包括與嗜酸性粒細胞增多症和全身症狀 (DRESS) 的藥物反應已有報告。 如果你發現與第 4 節中所述的嚴重皮膚反應有關的任何症狀，請停止服用氟康唑並立即就醫

使用其他藥物和莎華 -「婦康健」

請告訴你的醫生或藥劑師如果你最近服用過或可能服用了其他藥物。

請立即告訴你的醫生如果你正在服用阿司咪唑或特非那定(抗組織胺藥物治療過敏)，西沙必利(用於治療胃部不適)，匹莫齊特(用於治療精神疾病)，奎尼丁(用於治療心律不正)或紅霉素(一種治療感染的抗生素)，因為這些藥物不應與莎華 -「婦康健」一起服用(請參閱：「請勿使用莎華 -「婦康健」」)。

某些藥物可能與莎華 -「婦康健」產生相互作用確保你的醫生知道你正在服用以下任何一種藥物：

- 利福平或利福布丁(用於感染的抗生素)。
- 阿芬太尼，芬太尼(用作麻醉劑)。
- 阿米替林，去甲替林(用作抗抑鬱藥)。
- 兩性霉素 B，伏立康唑(抗真菌藥)
- 灌血藥以防止血栓(華法林或相類似藥物)
- 茶—茶皂(味連吸著，三唑啉或相類似藥物) 用於幫助睡眠或焦慮。
- 卡馬西平，奎安索(用於癲癇發作)。
- 硝苯地平，伊拉地平，氯氯地平，維拉帕米，非洛地平及洛沙坦(用於高血壓)。
- 奧拉帕米 (用於治療卵巢癌)
- 環孢素，依維莫司，西羅莫司或他克莫司(用於防止移植排斥反應)
- 環磷酰胺，長春花生物鹼(長春新鹼，長春鹼或類似藥物) 用於治療癌症。
- 維色素(用於治療感染)。
- 他汀類藥物阿托伐他汀，辛伐他汀及氟伐他汀或類似藥物用於降低高膽固醇水平。
- 美沙酮(用於疼痛)。
- 塞來昔布，氟比洛芬，泰普生，布洛芬，氯諾昔康，美洛昔康，雙氯芬酸（非類固醇抗炎症藥 - NSAIDs）。
- 口服避孕藥。
- 強的松類(糖醇)。
- 齊多夫定，也被稱為 AZT(沙奎那韋(用於愛滋病患者)。
- 糖尿病藥物如格列內脈，格列本脈，格列吡嗪或甲磺丁脈。
- 卡維地(用於控制哮喘)。
- 托法替尼（用於治療類風濕性關節炎）。
- 托伐普坦（用於治療低血鈉症 [低血鈉水平] 或減緩腎功能惡化）。
- 維他命 A (營養補充劑)。
- 依伐卡托（用於治療囊性纖維化）。
- 胺碘酮（用於治療心律不齊的“心律不正” ）。
- 氟氣哌喹（利尿劑）。
- 依魯替尼（用於治療血癌）。

服用莎華 -「婦康健」跟飲食

莎華 -「婦康健」可以在空肚或飽肚情況下服用。

懷孕及哺乳期婦女

如果你正在懷孕或哺乳，你認為可能懷孕或計劃生孩子，請在服用此藥之前諮詢你的醫生或藥劑師的建議。

如果你計劃懷孕，服用了單次劑量氟康唑後，建議你要等待一星期才嘗試懷孕。

對於較長療程的氟康唑治療，請諮詢你的醫生，以了解治療期間是否需要採取適當的避孕措施，並應在最後一次服藥後維持避孕一星期。

如果你懷孕，可能已經懷孕或計劃要嬰兒或哺乳，請不要服用氟康唑，除非你的醫生指示您這樣做。

如果你在服用此藥期間或最近一次服藥後一星期內懷孕，請諮詢你的醫生。

服用莎華 -「婦康健」150毫克單劑量後，你可以繼續母乳喂養。如果你重複服用莎華 -「婦康健」，請停止母乳喂養。

在懷孕初期或懷孕中期服用氟康唑可能會增加流產的風險。 在懷孕初期以低劑量服用氟康唑可能會稍微增加嬰兒出生患有影響心臟、骨骼或肌肉內的先天缺陷的風險

據報道，接受高劑量（每天 400-800毫克）氟康唑治療球孢子菌病三個月或更長時間的婦女中，出生時嬰兒的頭骨、耳朵、大腿和肘骨存在先天性畸形。氟康唑與這些病例之間的關係尚不清楚。

駕駛及操作機器

當你在駕駛或操作任何機器，應考慮到偶爾會出現頭暈或座暈的情況。

莎華 -「婦康健」含有乳糖

如果醫生告訴你對某些糖不耐受性，請在服用這種藥物之前先諮詢你的醫生。

莎華 -「婦康健」成分含有鈉

本產品的每膠囊含有少於 1 mmol (23mg) 的鈉；它基本上是“無鈉”的。

3. 如何使用莎華 -「婦康健」

請遵照醫生的指示使用莎華 -「婦康健」。如有疑問，請諮詢你的醫生或藥劑師。

莎華 -「婦康健」可用一杯開水整粒吞服。最好每天在同一時間服用你的藥物。

各種感染的常用藥物劑量如下：

成人

狀況	劑量
治療隱球菌性腦膜炎	第一日服用 400 毫克，然後每日一次 200 毫克至 400 毫克，持續 6 至 8 星期，在有需要時可加長時間。偶爾，劑量可增加至 800 毫克。
預防隱球菌性腦膜炎的復發	每日一次 200 毫克，直到你的醫生進一步給予指示。
治療球孢子菌病	每日一次 200 毫克至 400 毫克；使用 11 個月到 24 個月，或必要時延長；有需時可將劑量增加到 800 毫克。
治療由念珠菌引起的內部真菌感染	第一日 800 毫克，然後每日 400 毫克，直到你的醫生告訴你療程結束為止。