

ketoconazol cinfa 2% gel

Read all of this leaflet carefully before you start using this medicine because 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 any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Ketoconazol belongs to the group of medicines known as antifungals (medicines used to treat infections caused by fungi and yeast).

This medicine is indicated in adolescents and adults for the treatment and prevention of the following skin infections caused by fungi and yeast.

- *Pytiasis versicolor*, condition characterised by the onset of small irregular areas, brownish or whitish, distributed along the core.
- Seborrhoeic dermatitis, a condition that affects mainly the face and chest and cause skin reddening and flaking.
- *Pytiasis capitis* (dandruff), characterised by flaking of the scalp.

2. What you need to know before you start using ketoconazol cinfa

Don't use ketoconazol cinfa

If you are allergic to ketoconazol or any of the other ingredients of this medicine (listed in Section 6).

After application, some symptoms of allergy may be itching and irritation.

Warnings and precautions

Talk to your doctor or pharmacist before taking ketoconazol cinfa.

Only for external use. Avoid contact with the eyes. If there is accidental contact with the eyes, wash with plenty of water and consult an ophthalmologist if it were necessary.

If you are using corticosteroids in cream, ointment or lotion notify your doctor or pharmacist before starting treatment. You can start your treatment with this medication, but you must not stop applying it suddenly, since your skin might have a reaction and develop reddening or itching. Continue your treatment with corticosteroids as instructed below:

- Apply the same amount during the first week, gradually reduce the frequency over the course of the second to the third week.
- Stop using corticosteroids completely.

In the event of allergic reaction you must clean the gel off the skin, discontinue the treatment and go see your doctor immediately.

Children

The efficacy and safety of ketoconazol gel in children has not been evaluated.

Other medicines and ketoconazol cinfa

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

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.

As a precautionary measure it is preferable to avoid the use of this medicinal product during pregnancy and breast-feeding.

Driving and using machines

Given the characteristics of this medicinal product, there should be no impact on the ability to drive or use machines.

ketoconazol cinfa contains sodium lauryl sulphate

This medicinal product contains 480 mg of sodium lauryl sulphate in each ml. Sodium lauryl sulphate can cause local skin reactions (such as itching or burning sensation) or increase the skin reactions caused by other medicinal products when applied in the same area.

ketoconazol cinfa contains ethanol

This medicinal product contains 26.3 mg of alcohol (ethanol) in each ml. It can cause a burning sensation on injured skin.

3. How to use ketoconazol cinfa

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

The **frequency** of application and **duration** of treatment recommended for this medicinal product depend on the type of infection and whether it is a matter of treating or preventing the infection, and is as follows:

- *Pytiasis versicolor*: apply once daily for 5 days. For **prevention**, apply one single course once a day for 3 days in a row each year before summer.
- *Pytiasis capitis* (dandruff) and seborrhoeic dermatitis: apply twice each week, for 2-4 consecutive weeks. To prevent relapses after treatment, you can apply the gel once per week or once every 2 weeks. This prevents the symptoms from reappearing.

If symptoms do not improvement after 4 weeks of treatment, talk to a doctor.

Continue to use the gel until a few days after all symptoms have disappeared.

Elderly patients

There are no posological recommendations specific for these patients.

Form of use

Topical use.

The gel can be applied both on the scalp and on larger areas of the chest and face. Wash the infected areas of the skin or the scalp allowing the medicine to act for 3 to 5 minutes before washing it off. Make sure to wash both your skin and your hair. Normally, a handful of gel is sufficient for one washing.

If you take more ketoconazol cinfa than you should

If more ketoconazol is applied than your doctor has indicated, then you could feel a burning sensation or experience reddening or swelling that will subside when the treatment is discontinued.

Do not ingest this medicine. In the event of accidental ingestion, contact your doctor.

In case of overdose or accidental intake, consult your doctor or pharmacist immediately, specifying the medication and the amount taken.

If you forget to take ketoconazol cinfa

Do not take a double dose to make up for a forgotten dose.

If you stop taking ketoconazol cinfa

Do not stop the treatment without talking to your doctor first as your symptoms might reappear or worsen.

If you have any further questions on the use of 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.

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

- Burning sensation on the skin.
- Reddening of the skin at application site.
- Itching in the area of application.

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

- Inflammation of hair follicles.
- Allergic reaction (hypersensitivity).
- Increased tear production.
- Hair loss.
- Changes in hair texture.
- Localised eczema (contact dermatitis).
- Skin rash.
- Rash.
- Exfoliation of the skin (flaking).
- Oily, sticky skin.
- Other reactions at the administration site: bleeding, discomfort, dryness, inflammation, irritation, paresthesia (tingling, numbness).

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

- Distorted sense of taste.
- Eye irritation.
- Acne.
- Sensitive skin.

Not known (frequency cannot be estimated from the available data)

- Sudden swelling of the skin or the mucosa, usually of the face, eyes or lips.
- Changes in hair colour.
- Urticaria.

Stop the treatment in the event of intolerance to the gel.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible 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 ketoconazol cinfa

Keep this medicine out of the 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 temperatures above 25°C.

Do not throw away any medicines via wastewater or household waste. 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 ketoconazol cinfa contains

- The active substance is ketoconazol. Each millilitre of gel contains 20 mg of ketoconazol.
- The other components are: sodium lauryl ether sulphate, disodium lauryl ether sulphosuccinate, coconut fatty acid diethanolamine, hydrolysed collagen, macrogol 120 methylglucose dioleate, hydrochloric acid (E-507), imidazolidinylurea, summery perfume, erythrosine (E-127), sodium chloride and purified water.

Product appearance and contents of the pack

ketoconazol cinfa is marketed in the form of a red, viscous liquid gel.

It is packaged in high-density polyethylene bottles (HDPE), opaque white in colour with polypropylene cap (PP).

Each package contains a 100 ml bottle.

Marketing Authorisation Holder and Manufacturer

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Poligono Industrial Areta
31620, Huarte (Navarre) - Spain

DISTRIBUTOR

Reich Pharm Limited
Unit 3001, 30/F, Citicorp Centre,
18 Whitfield Road,
Hong Kong
Tel.: 2470 1059
Fax.: 2470 3448

HK Reg. No.: HK-54867

This leaflet was last revised in: May 2022.



莎華 -「膚康素」

在開始使用此藥物前, 請仔細閱讀本說明書, 因為它包含重要信息。

- 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。
- 此藥只處方給你個人使用, 因此你不應該把它交給別人使用。即使對方跟你的症狀很相似, 也可能造成傷害。
- 如果您有任何副作用, 請諮詢您的醫生或藥劑師。包括本說明書中未列出的任何可能的副作用。見第4節。

這張說明書內包含甚麼資料？

1. 莎華 -「膚康素」是甚麼及用於甚麼情況
2. 使用莎華 -「膚康素」前您需要留意甚麼
3. 如何使用莎華 -「膚康素」
4. 可能的副作用
5. 如何貯存莎華 -「膚康素」
6. 包裝及其他資料

1. 莎華 -「膚康素」是甚麼及用於甚麼情況？

酮康唑屬於稱為抗真菌藥的藥物類別（用於治療真菌和酵母感染的藥物）。

- 此藥用於青少年和成人於治療和預防由真菌和酵母引起的以下皮膚感染。
- 花斑癬, 其特徵在於沿著核心分佈的細小及不規則區域；褐色或帶白色的開始。
 - 脂溢性皮炎, 主要影響面部和胸部, 導致皮膚變紅和剝落。
 - 頭皮糠疹（頭皮屑）, 其特徵是頭皮剝落。

2. 使用莎華 -「膚康素」前您需要留意甚麼？

請勿使用莎華 -「膚康素」:

如果您對酮康唑或本藥的任何其他成分過敏(見第6節)。

使用後, 一些過敏症狀可能是瘙癢和刺激。

警告和注意事項

在使用莎華 -「膚康素」之前, 請諮詢您的醫生或藥劑師。

只供外用。避免接觸眼睛。如果不慎接觸到眼睛, 請用大量清水清洗, 如有必要, 請與眼科醫生聯絡。

如果您使用有皮質類固醇的霜劑、軟膏或乳液中, 請在開始治療前通知您的醫或藥劑師。您可以使用這種藥物開始治療, 但是您不能突然停止使用, 因為您的皮膚可能會出現反應並出現發紅或瘙癢。按照以下說明繼續使用皮質類固醇進行治療:

- 在第一周使用相同份量, 在第二周到第三週逐漸減少使用頻率。
- 完全停止使用皮質類固醇。

如果出現過敏反應, 您必須清除皮膚上的凝膠, 請停止治療並立即去看醫生。

兒童

尚未評估酮康唑凝膠在兒童中的有效性和安全性

其他藥物和莎華 -「膚康素」

如果您正在使用, 最近使用或可能使用任何其他藥物, 請告訴您的醫生或藥劑師。

懷孕及哺乳期

如果您懷孕或哺乳, 認為您可能懷孕或計劃生孩子, 請在服用此藥前諮詢您的醫生或藥劑師。

作為預防措施, 最好不要在懷孕和哺乳期間使用此藥。

駕駛及操作機器

鑑於此藥品的特性, 應不會影響駕駛或使用機器的能力。

莎華 -「膚康素」含有十二烷基硫酸鈉

此藥物每毫升含有480毫克十二烷基硫酸鈉。十二烷基硫酸鈉可引起局部皮膚反應（如瘙癢或灼熱感）或在同一區域使用其他藥物時會增加其他藥物引起的皮膚反應。

莎華 -「膚康素」含有乙醇

此藥物每毫升含有26.3毫克酒精（乙醇）。它會在受傷的皮膚上引起灼熱感。

3. 如何使用莎華 -「膚康素」

根據您的醫生或藥劑師吩咐使用該藥。如果您不確定, 請向您的醫生或藥劑師查詢。

此藥的建議劑量和治療持續時間取決於感染的類型以及是用於治療還是預防感染, 具體如下:

- 對於花斑癬的治療, 每天使用1次, 持續使用5天。為預防起見, 每年夏季前連續使用3天, 每天使用1次, 為一次性的治療。
- 頭癬（頭皮屑）和脂溢性皮炎: 每週使用2次, 連續使用 2至4 週。 為防止治療後復發, 您可以每週或每2週使用一次凝膠。這可以防止症狀再次出現。

如果治療4週後症狀沒有改善, 請諮詢醫生。

請繼續使用凝膠, 直至所有症狀消失後幾天。

老年患者

沒有針對這些患者的具體劑量學建議。

使用方法:

只供外用。

凝膠可以應用於頭皮及較大位置的胸部和面部。 清洗皮膚或頭皮的感染位置, 讓藥物在洗滌之前停留在受感染位置3至5分鐘。 一定要清洗乾淨你的皮膚和頭髮。通常少量凝膠已足夠一次洗滌。

假如使用莎華 -「膚康素」多於你應使用份量

如果使用的酮康唑比醫生指示的多, 那麼您可能會感到灼熱感或出現發紅或腫脹, 當停止治療時會消退。

請不要攝入此藥。如果意外攝入, 請聯繫您的醫生。

如果服用過量或意外攝入, 請立即通知您的醫生或藥劑師, 說明藥物和攝入量。

假如您忘記使用莎華 -「膚康素」

不要使用雙倍劑量來彌補你忘記使用的份量。

假如您停止使用莎華 -「膚康素」

不要在未諮詢醫生的情況下停止治療, 因為症狀可能會再次出現或惡化。

如果您對使用此藥有任何疑問, 請諮詢您的醫生或藥劑師。

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。儘管並不是每個人都會有此情況。

常見的副作用（每10名患者中最多可能有1位受影響）

- 皮膚有灼熱感。
- 應用部位皮膚變紅。
- 應用範圍瘙癢。

不常見的副作用（每100名患者中最多可能有1位受影響）

- 毛囊炎症
- 過敏反應（過敏）。
- 增加淚液製造
- 眩暈
- 頭髮質地變化
- 局部濕疹（接觸性皮炎）。
- 皮疹。
- 疹
- 皮膚表皮（剝落）
- 油性、黏性的皮膚。
- 塗抹的位置其他反應：出血、不適、乾燥、炎症、刺激、感覺異常（刺痛、麻痺）。

罕見的副作用（每1,000名患者中最多可能有1位受影響）

- 味覺障礙
- 眼睛不適
- 痤瘡
- 敏感皮膚

未知頻率(無法根據可用數據估算頻率):

- 皮膚或黏膜突然腫脹, 通常在臉部, 眼睛或嘴唇上
- 頭髮顏色的變化
- 荨麻疹

如果對凝膠不耐受, 請停止治療。

報告副作用

如果您有任何副作用, 請諮詢您的醫生或藥劑師。 這包括本說明書中未列出的任何可能的副作用。 通過報告副作用, 您可以幫助提供有關此藥物安全性的更多信息。

5. 如何貯存莎華 -「膚康素」

請將藥物存放於兒童不能觸及和視線範圍以外。

在藥盒上“EXP”註明的日期之後, 請勿使用此藥。到期日是指該月的最後一天。

請勿貯存於攝氏25度以上。

請勿通過廢水或家居垃圾丟棄任何藥物。 諮詢藥劑師如何丟棄不再使用的藥物。 這些措施將有助於保護環境。

6. 包裝及其他資料

莎華 -「膚康素」包含什麼:

- 主要成分是酮康唑。每毫升凝膠含有20毫克酮康唑。
- 其他成分是: sodium lauryl ether sulphate, disodium lauryl ether sulphosuccinate, coconut fatty acid diethanolamine, hydrolysed collagen, macrogol 120 methylglucose dioleate, hydrochloric acid (E-507), imidazolidinylurea, summery perfume, erythrosine (E-127), sodium chloride and purified water.

產品外觀及包裝內容

莎華 -「膚康素」以紅色粘性液體凝膠形式銷售。

它採用高密度聚乙烯瓶子 (HDPE) 包裝, 呈不透明白色及帶有聚丙烯的瓶蓋 (PP)。

每個包裝包含一個100毫升的瓶子。

營銷持有人及製造商

LABORATORIOS CINFA, S.A.
Carretera Olaz-Chipi, 10 Poligono Industrial Areta
31620 Huarte (Navarre) - Spain

代理商

漢生醫藥有限公司
香港威非路道18號萬國寶通中心30樓3001室
電話: 2470 1927
傳真: 2470 3448

HK Reg. No.HK-54867

本說明書的最新修訂於:2022年5月

PR031767E16-22002