

paracetamol cinfa 1 g tablets

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

- Keep this leaflet. You may need to read it again.
- If you have any 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 signs of illness 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 paracetamol cinfa is and what it is used for
2. What you need to know before you take paracetamol cinfa
3. How to take paracetamol cinfa
4. Possible side effects
5. How to store paracetamol cinfa
6. Contents of the pack and other information

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

Paracetamol cinfa belongs to a group of medicines called analgesics and antipyretics.

It is used for the symptomatic treatment of mild to moderate pain and fever in adults and adolescents over 15 years of age and weighing over 50 kg.

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

Do not take paracetamol cinfa

- If you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking paracetamol cinfa.

- Do not take more than the dose recommended in section 3, “How to take paracetamol cinfa”.
- Simultaneous use of this medicine with other medicines containing paracetamol, such as medicines for the common cold, should be avoided, since high paracetamol doses may damage the liver. Do not use more than one medicine containing paracetamol without first consulting the doctor.
- Chronic alcoholics should take care not to take more than 2 g of paracetamol in 24 hours.
- Because it contains 1 g of paracetamol, patients with kidney disease cannot take this medicine. Patients with liver, heart or lung diseases and patients with anaemia must consult their doctor before taking this medicine.
- When being treated with a medicine for epilepsy you should consult your doctor before taking this medicine because when used at the same time, there is reduced efficacy and increased liver toxicity of paracetamol, especially in treatments with high doses of paracetamol.
- Talk to your doctor before taking this medicine if you have asthma and are sensitive to aspirin.
- Paracetamol may cause serious skin reactions such as *acute generalised exanthematous pustulosis* (AGEP), Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN), that may prove fatal. Patients are to be informed about the signs of serious skin reactions, and the medicine should be suspended at the first sign of skin rash or any other sign of hypersensitivity.

Children and adolescents

Because of its paracetamol dose, this medicine should not be used in children or adolescents under 15 years of age (and weighing less than 50 kg).

Ask your doctor or pharmacist about the other available presentations allowing adequate dosing in such patients.

Interaction with laboratory tests

If you are going to have a laboratory test (including blood or urine tests, etc.), tell the doctor that you are taking this medicine, since it can alter the test results.

Paracetamol may alter the values of the laboratory test measurements of uric acid and glucose.

Other medicines and paracetamol cinfa

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

In particular, if you are using any of the following medicines, since it may be necessary to modify the dose of some of them or discontinue the treatment:

- Medicines to prevent blood clots: Oral anticoagulants (acenocoumarol, warfarin).
- Medicines to treat epilepsy: Antiepileptic agents (lamotrigine, phenytoin or other hydantoins, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Medicines to treat tuberculosis (isoniazid, rifampicin).
- Medicines to treat depression and seizures: Barbiturates (used as hypnotics, sedatives and anticonvulsants).
- Medicines used to lower blood cholesterol (cholestyramine).
- Medicines used to increase urine output (loop diuretics such as furosemide).
- Medicines used to treat gout (probenecid and sulphinyprazone).
- Medicines used to prevent nausea and vomiting: metoclopramide and domperidone.
- Medicines used to treat high blood pressure (hypertension) and heart rhythm abnormalities (arrhythmias): propranolol.

Also tell your doctor or pharmacist if you are taking:

- Flucloxacilin (antibiotic), due to a serious risk of blood and fluid disturbance (metabolic acidosis with high anion imbalance) which must be treated urgently. It can occur particularly in case of severe renal failure, sepsis (when bacteria and their toxins circulate in the blood resulting in organ damage), malnutrition, chronic alcoholism and if maximum daily doses of paracetamol are used.

Paracetamol cinfa with food, drink and alcohol

The use of paracetamol by patients who regularly consume alcohol (three or more alcoholic beverages - beer, wine, spirits - a day) may cause liver damage.

Taking this medicine with food does not affect its efficacy.

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.

If necessary, paracetamol cinfa can be used during pregnancy. It is important to use the lowest possible dose that reduces the pain or fever and it should be used for as short a time as possible. Talk to your doctor if the pain or fever does not decrease or if you need to take the medicine more often.

Paracetamol enters breast milk and, therefore, breast-feeding women should ask their doctor or pharmacist before taking this medicine.

Driving and using machines

Paracetamol has no or negligible influence on the ability to drive and use machines.

3. How to take paracetamol 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.

This medicine is taken orally.

According to your preference, tablets should be swallowed directly or split into two and taken with a glass of liquid, preferably water.

The recommended dose is:

Adults and adolescents over 15 years of age and weighing over 50 kg

The recommended dose is one or half a tablet (1 g - 500 mg of paracetamol), as required. At least 4 hours should be left between doses. More than 4 tablets (4 g) must not be taken in 24 hours.

Elderly patients

Your doctor will tell you the frequency and whether the dose needs to be reduced.

Patients with liver diseases

You should take the minimum amount of medicine prescribed by your doctor and leave at least 8 h between each dose. You must not take more than 2 grams of paracetamol in 24 hours, distributed over 2 doses.

Patients with kidney diseases

Consult your doctor before taking this medicine. The maximum quantity is half a tablet (500 mg) per dose. Depending on your illness, your doctor will tell you whether the medicine should be taken with an interval of at least 6 or 8 hours.

Do not take more than 2 grams of paracetamol in 24 hours in several doses, and in no case should the quantity exceed 500 mg per dose.

Children and adolescents

Do not use in children under the age of 15.

The tablet can be divided into equal doses.

This medicine should only be taken when the symptoms (pain or fever) are present. As the symptoms subside, the treatment should be discontinued.

High daily doses of paracetamol for long periods of time are to be avoided, since they increase the risk of adverse effects such as liver damage.

If the pain lasts for more than 5 days, the fever for more than 3 days, or either the pain or fever worsens or other symptoms appear, you should consult your doctor and reassess the clinical situation.

If you take more paracetamol cinfa than you should

In case of an overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

The symptoms of overdose may be: dizziness, vomiting, loss of appetite, yellow colouring of the skin and the eyes (jaundice), and abdominal pain.

In the event of an overdose, quickly report to a medical centre even if there are no symptoms, since these often only appear up to three days later, even in cases of severe intoxication.

In the event of overdose, its treatment is more effective if started within four hours after the overdose.

In patients treated with barbiturates, or in patients with chronic alcoholism, a paracetamol overdose may be more toxic than in the rest of patients.

If you forget to take paracetamol cinfa

Do not take a double dose to make up for missed doses, just take the forgotten dose when you remember and take subsequent doses with the time between doses indicated in each case (at least four hours).

If you stop taking paracetamol cinfa

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.

The possible side effects are:

Rare side effects (can affect 1 out of every 1000 people): malaise, lowered blood pressure (hypotension) and increased blood transaminase levels.

Very rare side effects (can affect up to 1 out of every 10,000 people): kidney diseases, cloudy urine, allergic dermatitis (skin rash), jaundice (yellow skin colour), blood abnormalities (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar). Very rarely cases of severe skin reactions have been reported.

Paracetamol may damage the liver when taken at high doses or during prolonged treatments.

Reporting of side effects

Talk to your doctor or pharmacist if you experience any kind of side effects, even if they are 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 paracetamol cinfa

Keep this medicine out of the sight and reach of children.

Do not store at a temperature above 25°C.

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 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 paracetamol cinfa contains

The active substance is paracetamol. Each tablet contains 1 g of paracetamol.

The other ingredients are: gluten-free pregelatinised corn starch, stearic acid, povidone, crospovidone, microcrystalline cellulose (E-460) and magnesium stearate (vegetable origin).

What the product looks like and contents of the pack

Paracetamol cinfa 1 g tablets are supplied in the form of oblong, biconvex scored white tablets for administration via the oral route.

The product is supplied in packs containing 20 tablets, packed in PVC-PVDC/ALU blisters.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta,
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莎華 - 「息疼樂」1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，請諮詢你的醫生或藥劑師，此包括任何未有在此說明書列出的任何可能的副作用。請參閱第4節。

此說明書包含甚麼資料？

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

1. 莎華 - 「息疼樂」是甚麼及用於甚麼情況

莎華 - 「息疼樂」屬於止痛和退燒藥物類別。
適用於15歲以上及體重50公斤以上的成人和青少年治療輕度至中度疼痛和發熱的症狀。

2. 使用莎華 - 「息疼樂」前你需要留意甚麼

請勿使用莎華 - 「息疼樂」

- 如你對莎華 - 「息疼樂」主要成份撲熱息痛(paracetamol)或其他任何成份過敏。請參閱第6節

警告和預防措施

- 服用莎華 - 「息疼樂」之前，請先諮詢你的醫生或藥劑師。
- 不要超過在第3節中建議的劑量，如何服用莎華 - 「息疼樂」
- 應避免與其他含有對撲熱息痛的藥物同時使用，例如流感和感冒藥，因為高劑量的撲熱息痛可能會損害肝臟。在未事先諮詢醫生的情況下，請勿使用多於一種含撲熱息痛的藥物。
- 慢性酗酒者應注意在 24小時內服用的撲熱息痛不要超過 2克。
- 因為它含有1克撲熱息痛，腎病患者不能服用此藥。患有肝臟、心臟或肺部疾病的患者和貧血患者在服用此藥前必須諮詢醫生。
- 當使用癲癇藥治療時，應先諮詢醫生，因為同時使用會降低對撲熱息痛的功效，並且肝臟毒性會增加，特別是使用高劑量撲熱息痛高劑量治療。
- 撲熱息痛可能引起嚴重的皮膚反應，例如急性廣泛性發疹性膿胞病 (AGEP)、史提芬斯-強森綜合症 (SJS) 或中毒性表皮壞死松解症 (TEN)，這些反應可能會致命。應告知患者嚴重皮膚反應的跡象，一旦出現皮疹或任何其他過敏跡象，應暫停用藥。

兒童和青少年

- 由於撲熱息痛的劑量，此藥不應用於15歲以下（及體重小於 50 公斤）的兒童或青少年。請諮詢您的醫生或藥劑師關於其他可用的藥物，以便此類患者獲得合適的劑量。

與實驗室測試的互動

如果你要進行任何實驗室測試(包括：血液或尿液測試，皮膚過敏原測試等)，請告訴你的醫生你正在服用本藥，因為它可能會改變測試結果。
撲熱息痛可能會改變尿酸和葡萄糖的分實驗室測試值。

其他藥物與莎華 - 「息疼樂」

- 如果你正在服用，最近服用或將會服用其他藥物，請告訴你的醫生或藥劑師。
- 特別是如果你正在使用以下任何一種藥物，你可能需要改變一些藥物的劑量或停止治療。
- 藥物以預防血液凝固：口服抗凝血劑(醋硝香豆素，華法林)
- 治療癲癇的藥物：抗癲癇藥物(拉莫三嗪，苯妥英鈉或其他乙內酰脲，苯巴比妥，甲基苯巴比妥，撲米酮，卡馬西平)
- 治療肺結核的藥物(異煙肼，利福平)
- 治療抑鬱症和癲癇發作的藥物：巴比妥類藥物(用作催眠藥，鎮靜劑和抗驚厥藥)
- 用於降低血液中膽固醇水平的藥物(消膽胺)
- 用於增加尿量的藥物(利尿劑如呋塞米組藥物)
- 用於治療痛風的藥物(丙磺舒和苯磺唑酮)
- 用於預防噁心和嘔吐的藥物：甲氧氯普胺和多潘立酮
- 用於治療高血壓(血壓高)和心律不正(心律失常)的藥物：普萘洛爾

如果您正在以下藥物服用，請告訴您的醫生或藥劑師：

- 氟氯西林（抗生素），由於存在嚴重的血液和體液紊亂風險（高陰離子失衡的代謝性酸中毒），必須緊急治療。特別是在嚴重腎功能衰竭、敗血症（當細菌及其毒素在血液中循環導致器官損傷）、營養不良、慢性酒精中毒以及使用每日最高劑量的撲熱息痛的情況下會發生這種情況。

莎華 - 「息疼樂」與食物, 飲料和酒精

經常喝酒的患者（每天喝三杯或更多酒精飲料-啤酒，葡萄酒，烈酒）使用撲熱息痛可能會造成肝臟損害。
與食物一起服用本藥不會影響其功效。

懷孕和哺乳期

如果你正在懷孕或哺乳期，認為你可能已經懷孕或打算生孩子，請在服用此藥物之前諮詢你的醫生或藥劑師諮詢。
如有必要，可在懷孕期間使用撲熱息痛。重要的是盡可能使用最低的劑量以減輕疼痛或發燒，並且應盡可能短暫使用。如果疼痛或發燒沒有減輕，或者你需要更頻繁地服藥，請諮詢你的醫生。

撲熱息痛會進入母乳，因此，哺乳期婦女在使用此藥物之前應諮詢醫生。

駕駛及操作機器

撲熱息痛對駕駛或使用機器的能力沒有影響或影響很小。

3. 如何服用莎華 - 「息疼樂」

請遵照醫生或藥劑師的指示服用此藥物。如有疑問，請諮詢你的醫生或藥劑師。

此藥只供口服。

根據你的喜好，可以直接將整粒藥丸吞服，或將其分成兩半，又或者用一杯液體（最好是開水）的幫助下服用。

建議劑量為：

成人和15歲以上的青少年（且體重超過50公斤）：
成人建議劑量為1片至半片（1克至500毫克撲熱息痛）。每次劑量必須相隔至少4小時，並且在24小時內不可服用超過4片(4克)。

老年患者：

您的醫生會告訴您服用此藥物次數以及是否需要減少劑量。

肝病患者：

在服用本藥物之前，你應該先諮詢你的醫生，並且服用醫生規定的藥量，每次相隔最少應相隔8小時。在24小時內，不應服用超過2克撲熱息痛，並分成2次服用。

腎病患者：

在服用本藥物之前，你應該先諮詢你的醫生。每次最多服用半粒(500毫克)。根據你的病況，你的醫生會告知你每次相隔最少6或8小時服藥。在24小時內，不應服用超過2克撲熱息痛，並分成多次服用，每次不應超過500毫克。

兒童和青少年

15歲以下請勿服用。

片劑可平均分成相等劑量。

只有在出現症狀（疼痛或發燒）時才應服用此藥。隨著症狀消退，應停止治療。

應避免長時間每天服用高劑量的撲熱息痛，因為它們會增加肝損傷等不良反應的風險。

如果疼痛持續超過5天，發燒超過3天，或者疼痛或發燒惡化或出現其他症狀，您應該諮詢您的醫生並重新評估臨床情況。

假如服用莎華 - 「息疼樂」多於你應服用份量

如果過量或意外服用，請立即通知您的醫生或藥劑師，說明藥物名稱和攝取量。

服藥過量的症狀可能包括：頭暈，嘔吐，食慾不振，皮膚和眼睛的顏色變黃(黃疸)和腹痛。

如果你服用過量，即使你沒有任何症狀，也應立即向醫療中心報告，因為即使在嚴重中毒的情況下，因為病徵通常在服用後3天才會出現。

處理過量服用藥物時, 在服用藥物後4小時內進行是最有效的。

用巴比妥類藥物（鎮靜劑的一種）治療的患者或長期酗酒者的患者,可能更容易受到撲熱息痛過量的毒性作用影響。

假如你忘記服用莎華 - 「息疼樂」

請勿服用雙倍劑量來彌補遺忘的劑量。

當您記得時便服用遺忘了的劑量，並在每種情況下按指示的劑量之間的時間（至少四個小時）服用後續劑量。

假如你停止服用莎華 - 「息疼樂」

如果您對該藥的使用有任何疑問，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，儘管並不是所有人都會有此情況。

罕見的副作用(每1,000人中最多可能會有1個人受影響)：不適，血壓降低（低血壓）和血液轉氨酶水平升高。

非常罕見的副作用(每10,000人中最多可能會有1個人受影響)：腎臟疾病，尿液混濁，嚴重的皮膚反應，過敏性皮炎（皮疹），黃疸（皮膚顏色為黃色），血液異常（粒細胞缺乏症，白細胞減少症，中性粒細胞減少症，溶血性貧血）和低血糖症（低血糖）。
很少有嚴重皮膚反應的病例。
服用高劑量或服用撲熱息痛治療可能會損害肝臟

報告副作用

如果你有任何副作用，請告訴你的醫生或藥劑師。這包括本說明書中未列出的任何副作用。通過報告副作用，你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 - 「息疼樂」

請將藥物存放於兒童不能觸及和視線範圍以外。
請勿貯存於攝氏25度以上。

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最後一日。

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 - 「息疼樂」包含什麼：

主要成份是撲熱息痛(paracetamol)。每片含1克撲熱息痛。
其他成份包括：gluten-free pregelatinised corn starch, stearic acid, povidone, crospovidone, microcrystalline cellulose (E-460) and magnesium stearate (vegetable origin)。

莎華 - 「息疼樂」的外觀和包裝

莎華 - 「息疼樂」1克薄膜衣片劑為長方形，雙凸刻痕白色片劑，口服藥物。
每盒20粒薄膜衣片劑，採用 PVC/PVDC/鋁泡罩包裝。

製造商及營銷持有人

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