

paracetamol cinfa 650 mg 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 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 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 belongs to a group of medicines called analgesics and antipyretics.

It is indicated to treat the symptoms of mild to moderate and pain and fever. You must talk to a doctor if your fever worsens or does not improve after 3 days or pain after 5 days.

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

Do not take paracetamol cinfa

- If you are allergic to paracetamol, propacetamol hydrochloride 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 exceed the dose recommended in section 3. “How to take paracetamol cinfa”.
- Asthmatic patients who are sensitive to acetylsalicylic acid should consult their doctor before taking this medicine.
- If you suffer from liver, kidney, heart or lung disease or you have anaemia (reduced blood haemoglobin, whether because of reduced red blood cells or not), you should consult your 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.
- Chronic alcoholics should take care not to take more than three 650 mg tablets of paracetamol in 24 hours.
- 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.

Children and adolescents

For children and adolescents under 15 years old consult your doctor or pharmacist as there are other presentations with a dose adapted to this group of patients.

Other medicines and paracetamol cinfa

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

Paracetamol may interact with the following medicines:

- 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.

Simultaneous use with other analgesics (medicines used to treat pain) is to be avoided, unless approved by the doctor.

As a general rule, for any medicine it is recommended that you systematically notify the doctor or pharmacist if you are in treatment with another medicine. In case of treatment with oral anticoagulants, it may be administered occasionally as the analgesic of choice.

Interaction with laboratory tests

If you are to undergo any tests (blood or urine tests, skin tests with allergens, etc.), tell your doctor that you are taking this medicine because it may alter the results of such tests.

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.
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Taking this medicine with food does not affect its efficacy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before using any medicine.

IMPORTANT NOTE FOR WOMEN 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. The use of medicines during pregnancy can be dangerous for the embryo or foetus and must be monitored by your doctor.

Pregnancy

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 do not decrease or if you need to take the medicine more often.

Breast-feeding

Small amounts of paracetamol may appear in breast milk; therefore, it is recommended you consult your 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.

paracetamol cinfa contains sodium

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

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.

Remember to take your medicine. Paracetamol should be taken by mouth.

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

The recommended dose is:

Adults and adolescents over 15 years old: the recommended dose is 1 tablet (650 mg of paracetamol) every 4 to 6 hours. At least 4 hours should be left between doses. Do not take more than 6 tablets in 24 hours.

Patients with liver disease: must consult their doctor before taking this medicine. You should take the minimum amount of medicine prescribed by your doctor and leave at least 8 h between each dose. Do not take more than three 650 mg paracetamol tablets in 24 hours.

Patients with kidney disease: must consult their doctor before taking this medicine. The maximum quantity is 500 mg per dose. Due to the dose, 650 mg of paracetamol, the medicine is not indicated for this group of patients.

Elderly patients: must consult their doctor.

Use in children and adolescents: Do not use in children under the age of 15.

If your think the effects of this medicine are too strong or too weak, tell your doctor or pharmacist.

If you take more paracetamol cinfa than you should

Immediately contact your doctor or pharmacist.

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 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.

The period in which the management of overdose offers maximum efficacy is within four hours after overdose.

Patients treated with barbiturates or patients with chronic alcoholism may be more susceptible to paracetamol overdose toxicity.

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

If you forget to take paracetamol cinfa

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

4. Possible side effects

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

Rare side effects (may affect up to 1 in 1,000 people): malaise, lowered blood pressure (hypotension) and increased blood transaminase levels. Very rare side effects (may affect up to 1 in 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

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 paracetamol cinfa

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

Do not store at temperatures 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 650 mg of paracetamol.
- The other ingredients (excipients) are sodium carboxymethyl starch (type A) (from potato), purified water, pregelatinised maize starch, povidone K30 (E-1201), stearic acid (E-570) and crospovidone (E-1202).

What paracetamol cinfa looks like and contents of the pack

Oblong, biconvex, white tablets, scored on one side and marked with “PB” on the other side.

Packs of 20, 40 or 500 (clinical pack) tablets, packaged in PVC/PVDC/aluminium blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

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

Manufacturer:

SAG Manufacturing S.L.U.
Ctra. N-I, Km 36
San Agustín de Guadalix
28750 Madrid - Spain

Distributor:

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HK Reg.No. : 63129

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莎華 -「息疼樂」650 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。

用於治療輕度至中度和疼痛和發燒的症狀。如果您的發燒在3天後惡化或沒有改善或在5天後出現疼痛，您必須諮詢醫生。

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」

- 如果您對撲熱息痛 (paracetamol)、鹽酸撲熱息痛或此藥的任何其他成份過敏。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」
- 對乙酰水楊酸敏感的哮喘患者應在服藥前諮詢醫生。
- 如果你患有肝，腎，心臟或肺部疾病，或者患有貧血（無論是否由於紅血球減少而導致的血紅蛋白減少）您應在服用此該藥之前諮詢您的醫生。
- 當使用癲癇藥治療時，應先諮詢您的醫生，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。
- 慢性酗酒者應注意不要在24小時內服用超過3片 650 毫克撲熱息痛。
- 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。

兒童和青少年

兒童和在15歲以下的青少年，請與你的醫生或藥劑師聯絡，因為可能有其他更合適劑量的撲熱息痛產品可用於這些患者。。

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。

撲熱息痛可能與以下藥物有相互作用：

- 預防血液凝塊的藥物：口服抗凝藥（醋硝香豆素，華法林）。
- 治療癲癇的藥物：抗癲癇藥（拉莫三嗪、苯妥英或其他乙內酰脲、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）。
- 降低血液膽固醇的藥物（消膽胺）。
- 增加尿量的藥物（袪利尿劑，如速尿）。
- 治療痛風的藥物（丙磺舒和磺胺吡酮）。
- 預防噁心和嘔吐的藥物：甲氧氯普胺和多潘立酮。
- 治療高血壓（高血壓）和心律異常（心律失常）的藥物：普萘洛爾。

如果您正在服用以下藥物，請告訴您的醫生或藥劑師：

- 氟氣西林（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（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。

除非得到醫生的批准，否則應避免與其他鎮痛藥（用於治療疼痛的藥物）同時使用。

在一般原則下，對於任何藥物，如果您正在使用另一種藥物進行治療，建議您有系統地通知醫生或藥劑師。在使用口服抗凝劑治療的情況下，可以偶爾選用它作為鎮痛劑。

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, 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。

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

在使用任何藥物之前，請諮詢您的醫生或藥劑師。

給女性的重要提示

如果您懷孕或哺乳，認為您可能懷孕或計劃生育，請在服用此藥前諮詢您的醫生或藥劑師。 懷孕期間使用藥物可能對胚胎或胎兒造成危險，必須由您的醫生進行監測。

哺乳期

母乳中可能會出現少量的撲熱息痛； 因此，建議您在服用此藥前諮詢您的醫生或藥劑師。

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。

莎華 -「息疼樂」含有鈉.

這種藥物每片含有少於23 毫克 (1 毫摩爾)的鈉；它基本上是“不含鈉”。

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。

記得服用你的藥。撲熱息痛應是口服的。

根據您的喜好，藥片應可直接吞服或分成兩份，然後與一杯液體（最好是水）一起服用。

藥片可分為等劑量。

建議劑量為：

成人和15歲以上的青少年:

建議劑量為每4-6小時服用1片（650毫克撲熱息痛）。每次服藥之相隔時間不可少於4小時。在24小時內不可要服用超過 6片藥片。

肝病患者: 在服用此藥之前必須諮詢他們的醫生。 您應該服用醫生處方的最低劑量的藥物，並且每次服藥之間至少相隔 8 小時。24小時內不要服用超過三片 650 毫克的撲熱息痛藥片。

腎病患者: 在服用此藥之前必須諮詢他們的醫生。 每次服用最高劑量為 500 毫克。由於此劑量為 650 毫克的撲熱息痛，此藥物不適用於這組患者。

老年患者: 必須諮詢他們的醫生。

用於兒童和青少年: 請勿用於15歲以下兒童。

假如服用莎華 -「息疼樂」多於你應服用份量

請立即聯繫您的醫生或藥劑師。

過量服用的症狀可能是：頭暈、嘔吐、食慾不振、皮膚和眼睛發黃（黃疸）和腹痛。

如果服用過量，即使沒有症狀，也應立即向醫療中心報告，因為病徵通常在服用後3天才會出現，即使在嚴重中毒的情況下也是如此。

服用過量藥物的情況, 在服用過量藥物後4小時內處理是最有效的。

接受巴比妥類藥物治療的患者或患有慢性酒精中毒的患者可能更容易受到撲熱息痛過量毒性的影響。

如果過量或意外攝入，請立即告訴您的醫生或藥劑師，說明藥物名稱和攝取量。

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。

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）。

服用高劑量或長期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的出任何副作用。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650毫克撲熱息痛。
- 其他成份包括：sodium carboxymethyl starch (type A) (from potato), purified water, pregelatinised maize starch, povidone K30 (E-1201), stearic acid (E-570) and crospovidone (E 1202)。

莎華 -「息疼樂」的外觀和包裝

莎華 -「息疼樂」650毫克薄膜衣片劑為長方形，包衣，雙凸，白色藥片，一側刻有記號，另一側有“PB”。

每盒 20、40 或 500 粒（臨床包裝）片劑，採用 PVC/PVDC/鋁泡罩包裝。

並非所有粒數包裝都在市場出售。

營銷持有人及製造商

營銷持有人

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