

INFORMATION LEAFLET: INFORMATION FOR THE USER

SICADOL

1000 mg, tablet

Paracetamol

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. 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, including any possible side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

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

1. What Sicadol is and what it is used for

Sicadol is a medicine used for pain relief and to reduce fever (analgesic and antipyretic).

It is used for the symptomatic treatment of clinical situations such as:

- flu-like or feverish conditions due to infections
- feverish reactions associated to vaccination
- headache and migraine
- toothache, earache, menstrual, traumatic, muscle and joint pain.
- pain relief before and after surgery

2. What you need to know before you take Sicadol

Do not take Sicadol

- if you are allergic (hypersensitive) to paracetamol or any of the ingredients of this medicine (see section 6)
- if you have a severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sicadol.

Take special care:

- if you have a liver disease (for example, inflammation of the liver caused by abuse of alcoholic drinks) or kidney disease.
- if you are taking other medicines containing paracetamol
- if you have severe haemolytic anaemia (abnormal decrease of the number of red blood cells)
- if you have a hereditary and rare metabolic disease called Gilbert's syndrome which is accompanied by increased blood bilirubin levels.

In these circumstances, you should consult your doctor before using the medicine.

Sicadol should not be used frequently for a long period of time, as prolonged use can cause liver problems. Please tell your doctor or pharmacist if you intend to take paracetamol for a long period of time.

Paracetamol should be used with precaution in situations of dehydration and chronic malnutrition.

If you suffer from alcoholism or have a liver disease do not use paracetamol unless prescribed by your doctor and do not take paracetamol simultaneously with alcoholic drinks. Paracetamol does not enhance the effect of alcohol.

If you are taking other painkillers at the same time which contain paracetamol, do not take Sicadol without first talking to your doctor or pharmacist.

Taking painkillers too often and for too long can cause headaches, which may not be treated with high doses of the medicine.

In general, the habitual ingestion of painkillers, in particular in combination with various analgesic substances, can lead to permanent kidney damage with risk of kidney failure (analgesic nephropathy).

Paracetamol should not be used in situations of high fever (above 39°C), fever lasting longer than 3 days or recurring fever, unless prescribed by a doctor, since these situations may require medical assessment and treatment.

Effects in patients with special diseases

If you suffer from liver or kidney disease or Gilbert's syndrome, talk to your doctor who will recommend you the appropriate dose and dosing intervals of paracetamol.

Children and adolescents

Paracetamol is intended to be taken by adults over 18 years old.

Other medicines and Sicadol

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

This is especially important in the following cases:

- chloramphenicol (to treat infections)
- zidovudine (to treat AIDS). Patients taking this substance at the same time as paracetamol may be more prone to develop a reduced number of white blood cells.
- rifampicin (to treat infections, e.g. tuberculosis)
- cimetidine (to treat heartburn)
- metoclopramide or domperidone (to treat nausea and vomiting)
- cholestyramine (to reduce cholesterol). Take paracetamol 1 hour before or 4 hours after taking cholestyramine.
- anticoagulants (medicines to prevent blood clotting, e.g. warfarin), in case it's necessary to take a medicine to relieve pain daily during a long period of time.
- carbamazepine, phenobarbital and phenytoin (to treat epilepsy).

Sicadol with food, drinks and alcohol

Do not take paracetamol simultaneously when consuming large quantities of alcoholic drinks.

Pregnancy, breastfeeding and fertility

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

During pregnancy, paracetamol should not be taken over long periods of time, in high doses or combined with other medicines.

Therapeutic doses of paracetamol can be taken during pregnancy and breastfeeding.

Driving and using machines

Paracetamol does not interfere with your ability to drive or operate machinery. However, it should be borne in mind that, during treatment with paracetamol, slight drowsiness and dizziness may occur as side effects.

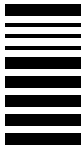
3. How to take Sicadol

Always take this medicine exactly as your doctor or pharmacist has told you.

If you are not sure, check with your doctor or pharmacist.

Doses

Sicadol is intended to be taken by adults.



The recommended dose of Sicadol is 1 tablet, 2 to 4 times a day. This dose may be repeated every 4 - 8 hours, according to the clinical situation.

Do not exceed the recommended dose.

The maximum daily dose is 4 tablets.

Special groups of patients:

Elderly patients: no dose adjustment is required for elderly patients.

If you suffer from liver or kidney disease or Gilbert's syndrome, talk to your doctor who will recommend you the appropriate dose and dosing intervals of Sicadol.

How to take

The tablets are taken orally.

The tablets may be swallowed whole or dissolved in water.

The score is only there to help break the tablet, in case of difficulty in swallowing it whole.

Taking tablets after meals may delay the onset of action.

If you take more Paracetamol than you should

In the event of an overdose, seek immediate medical advice, even if you feel well, because of the risk of delayed serious liver damage a few hours later.

The first signs of overdose include nausea, vomiting and strong stomach pain. Even if these signs improve temporarily, consult your doctor immediately.

If you forget to take Sicadol

If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. However, do not take a double dose to make up for a forgotten dose.

If you stop taking Sicadol

Suddenly stopping to take paracetamol after prolonged use can cause headaches, fatigue, muscle pain, nervousness, dizziness and fainting. These symptoms disappear after a few days. Until this happens, do not use other painkillers and treatment with these medicines should not be restarted without medical advice.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

At the recommended doses, paracetamol is usually well tolerated.

Frequent secondary effects (can affect >1/100 to < 1/10 patients):

- Mild drowsiness, nausea, vomiting

Infrequent (can affect >1/1,000 to < 1/100 patients):

- Dizziness, drowsiness, nervousness
- Burning sensation in throat
- Diarrhoea, stomach pain (including cramps and burning sensation), constipation
- Headache
- Perspiration/sweating, hypothermia

Rare (can affect >1/10,000 to < 1/1,000 patients):

- Redness of the skin

Very rare (can affect <1/10,000 patients):

- Blood disorders (change in blood cell count)
- Bronchospasm (narrowing of the airways) in predisposed people

- Allergic reactions, exacerbated hypersensitivity reactions to paracetamol, muscle spasms in the airways causing breathing difficulties, swelling of the face, sweating, nausea and decreased blood pressure (including shock).

When the first signs of allergic reactions appear, stop the treatment and immediately seek your doctor's advice.

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 Sicadol

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

Store below 25°C.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and further information

What Sicadol contains

The active substance is paracetamol. Sicadol contains 1,000 mg of paracetamol.

The other ingredients are pregelatinised starch, povidone and stearic acid.

What Sicadol looks like and contents of the pack

White, oblong tablets, scored on one side.

The score is only there to help break the tablet, in case of difficulty in swallowing it whole.

The tablets are packed in PVC/Aluminium blisters, in packs of 40 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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