

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sicadol Extra 500 mg/65 mg tablets
Paracetamol/Caffeine

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days (in case of fever) or, in case of pain, after 5 days.

- What is in this leaflet:**
1. What Sicadol Extra is and what it is used for
 2. What you need to know before you take Sicadol Extra
 3. How to take Sicadol Extra
 4. Possible side effects
 5. How to store Sicadol Extra
 6. Contents of the pack and other information

1. What Sicadol Extra is and what it is used for

Sicadol Extra contains paracetamol, an analgesic (pain killer) and antipyretic (reduces body temperature in case of fever), and caffeine, an adjuvant of paracetamol's analgesic effect (increases the pain relief effect).

Sicadol Extra is indicated in adults and children aged 12 years and over for the relief of fever and in the treatment of mild to moderate pain, including:

- Symptoms associated with flu-like syndromes and colds
- Headache, including migraine
- Toothache and pain due to dental interventions
- Sore throat
- Menstrual pain
- Muscle aches
- Post-traumatic pain

If you do not feel better or if you feel worse after 3 days (in case of fever) or, in case of pain, after 5 days, you must talk to a doctor.



An overdose of paracetamol may result in severe liver injury, kidney damage and death.

High doses of caffeine can cause headaches, tremor, nervousness and irritability.

The doctor will take appropriate treatment and appropriate support measures.

If you forget to take Sicadol Extra

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

If necessary, take the missed dose as soon as you remember. You can only take the medicine again after 4 hours. Then return to the recommended dosage schedule.

If you stop taking Sicadol Extra

The sudden interruption of medicines for pain (analgesics), after inappropriate and prolonged administration of high doses can cause headache, fatigue, muscle aches, irritability, among others. These symptoms disappear within a few days. Until the disappearance of these symptoms, do not take other analgesics or return taking Sicadol Extra unless by medical indication.

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.

At the recommended doses, Sicadol Extra is generally well tolerated.

Stop taking this medicine immediately and call your doctor if you experience swelling of the face, particularly around the mouth (lips, tongue, mouth and/or throat), difficulty in breathing, sweating, nausea or sudden drop in blood pressure. These symptoms may mean that you are having a severe allergic reaction that can put your life at risk, but which occurs very rarely.

Possible side effects of paracetamol

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

- Nausea
- Vomiting

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

- Vertigo
- Nervousness

2. What you need to know before you take Sicadol Extra

Do not take Sicadol Extra

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from severe liver disease
- acute hepatitis
- if you are under 12 years of age

Warnings and precautions

Do not take other medicines containing paracetamol, namely over the counter medication for pain relief, flu symptoms, fever, etc. while you are taking Sicadol Extra. Consult your doctor in case of persisting or worsening of symptoms.

Talk to your doctor or pharmacist before taking Sicadol Extra:

- if you have kidney problems
- if you have liver problems
- in case you suffer from alcoholism and/or chronic malnutrition
- if you have a high fever (higher than 39° C)
- if the fever lasts for more than 3 days
- if the fever disappears and then reappears (recurring fever)
- if the pain lasts for more than 5 days

The incorrect use of large quantities of medicines for pain (analgesics) for an extended period of time can cause headaches. Do not treat these headaches by increasing the dose of Sicadol Extra.

This medicine should not be used for self-medication of pain, for more than 5 days, except if prescribed by a doctor, because an intense and prolonged pain may require medical evaluation and treatment.

Do not exceed the recommended daily dose.

Children

Do not give this medicine to children younger than 12 years old.

Athletes are cautioned that Sicadol Extra contains an active substance (caffeine) which can induce positive anti-doping controls.



- Diarrhoea
- Abdominal pain (including cramps and burning)
- Constipation
- Headache
- Increased sweating/perspiration
- Excessive reduction of body temperature

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

- Mild increase of some liver enzymes (serum transaminases)
- Redness of the skin

Very rare side effects (may affect up to 1 in 10,000 people)

- Irritability
- Insomnia
- Blood disorders (reduction in the number of platelets; reduction of the number of white blood cells, sometimes intense; general decrease of all elements of the blood)
- Difficulty in breathing (analgesic asthma) in people who have had respiratory problems with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs
- Hypersensitivity reactions
- Severe cutaneous reactions

The prolonged use of Sicadol Extra may cause kidney damage.

Possible side effects of caffeine

Very rare side effects (may affect up to 1 in 10,000 people)

- Irritability
- Nausea
- Insomnia

If medicine is combined with caffeine in the food/drink, the incidence of caffeine undesirable effects such as insomnia, restlessness, anxiety, irritability, headache, gastrointestinal irritation (nausea) and palpitations is increased.

If any of the side effects worsen, or if you detect any side effects not mentioned in this leaflet, please talk to your doctor or pharmacist.

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. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

Other medicines and Sicadol Extra

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

- warfarin or other coumarin anticoagulants (medicines to prevent blood clotting)
- carbamazepine, phenobarbital and phenytoin (antiepileptics)
- rifampicin, chloramphenicol (medicines to treat bacterial infections)
- zidovudine (treatment of HIV and AIDS)
- metoclopramide, domperidone, propantheline (for the treatment of nausea, vomiting, gastric ulcers)
- cholestyramine (medicine that reduces the cholesterol in the blood)
- probenecid (lowers the uric acid in your body)
- flucloxacillin: there is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, particularly in certain groups of patients at risk, e.g. patients with severe renal impairment, sepsis or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

Do not take other medicines containing paracetamol during treatment with Sicadol Extra.

Sicadol Extra with food, drink and alcohol

Avoid drinks with caffeine (coffee, tea, soft drinks) while taking Sicadol Extra. High doses of caffeine may cause difficulty in sleeping, agitation and chest discomfort, due to the increase of the heart beating.

Do not drink alcohol whilst taking Sicadol Extra, since it may increase the risk of liver damage.

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.

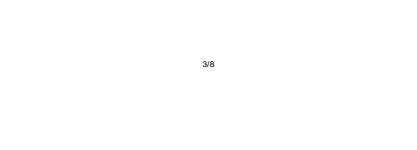
The administration of Sicadol Extra should be avoided during pregnancy and breast feeding, due to its caffeine content, unless otherwise indicated by a doctor. Contact your doctor if the symptoms are not reduced or if you need to take the medicine more often.

Driving and using machines

Sicadol Extra does not affect the ability to drive and use machines.

Sicadol Extra contains sodium.

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, i.e., is practically "sodium-free".



5. How to store Sicadol Extra

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton. 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 Sicadol Extra contains

- The active substances are paracetamol and caffeine. Each tablet contains 500 mg of paracetamol and 65 mg of caffeine.
- The other ingredients are maize starch, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, colloidal anhydrous silica.

What Sicadol Extra looks like and contents of the pack

Sicadol Extra are white oblong tablets, packed in PVC/PVDC-Al blister and carton box.

Pack size: 2, 4, 6, 8, 10, 12, 16, 20 tablets.

Not all pack sizes may be marketed.

3. How to take Sicadol Extra

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults (including the elderly) and children aged 15 years and over 50 kg:
1 to 2 tablets, 3 to 4 times per day (every 6 - 8 hours), as required.

Children 12-15 years (< 50 kg):
1 tablet, 3-4 times daily (every 6 - 8 hours), as required.

Maximum daily dose:

The dose of 3 g of paracetamol daily, i.e. 6 tablets per day should not be exceeded. An interval of 4 hours (at least) should always be observed between administrations.

The tablets should be swallowed with a sufficient amount of water.

Duration of the treatment

Medicines containing paracetamol should not be taken in high doses, except if prescribed by a doctor.

If you do not feel better or if you feel worse after 3 days (in case of fever) or, in case of pain, after 5 days, you must talk to a doctor.

Use in children younger than 12 years old

Do not give Sicadol Extra to children under 12 years of age.

Patients with kidney or liver impairment

Patients with liver or kidney problems should talk to a doctor before taking this medicine, because they may need a more suitable dose and/or interval between administrations.

If you take more Sicadol Extra than you should

In case of overdose or accidental ingestion by child, go immediately to your doctor or to the nearest hospital and tell them exact amount of Sicadol Extra you have taken. Show them used package and this package leaflet.

The symptoms of overdose of paracetamol are nausea, vomiting, loss of appetite, pallor, and abdominal pain, usually appearing within the first 24 hours. Seek medical help immediately, even if you do not have these symptoms, since you may have severe liver damage or failure without realising it.



Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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