**Package leaflet: Information for the patient**

**Paracetamol Sandoz® 1000 mg, tabletten**

Paracetamol

[For medicines available with a prescription]
**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.

[For medicines available without a prescription]
**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
Always take 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 5 days for pain or after 3 days for fever.

**What is in this leaflet**


## 1. What [nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance paracetamol. It is a pain relieving, fever reducing medicine (analgesic and antipyretic).

[Nationally completed name] 1000 mg is used for mild to moderate pain and/or fever in adults and adolescents aged 15 years and older.

## 2. What you need to know before you take [nationally completed name]

**Do not take [nationally completed name]**
- if you are allergic (hypersensitive) to paracetamol or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Do not take more medicine than recommended in paragraph 3 " How to take [nationally completed name]".
- Simultaneous use of this medicine with other medicines containing paracetamol, for example medicines for influenza and cold, should be avoided as high doses can lead to liver damage. Do not use more than one medicine containing paracetamol without talking to your doctor.
- Chronic alcoholics should be careful not to take more than 2 grams in 24 hours of paracetamol.
- Patients with kidney, liver (including Gilbert's syndrome), heart or lung disease and patients with anaemia should consult their doctor before taking this medicine.
- When you are being treated with any medication to treat epilepsy you should consult the doctor before taking this medication, because when used at the same time, the efficacy and hepatotoxicity of paracetamol is decreased, especially in treatments with high doses of paracetamol.
- Asthmatic patients sensitive to acetylsalicylic acid should consult with the doctor before taking this medicine

Talk to your doctor or pharmcaist before taking [nationally completed name] in case of:
- an inherited deficiency of a certain enzyme called Glucose-6-phosphate dehydrogenase
- abnormal breakdown of red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- a lack of total body water (dehydration)
- underweight or chronic malnutrition
- glutathione depletion (severe malnutrition, anorexia, low body mass index, chronic alcoholism, sepsis)

During treatment with [nationally completed name], tell your doctor straight away if:

You have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

**Other medicines and [nationally completed name]**
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Especially talk to your doctor or pharmacist before taking [nationally completed name], if you are taking any of the following medicines:

- other medicines containing paracetamol, such as, for example, some medicines for cold and flu. Take care not to exceed the maximum daily dose of paracetamol since this may severely damage the liver.

- other medicines that are known to affect the liver
- medicines which induce liver enzymes such as:
  - barbiturates such as phenobarbital (group of anesthetics and medicines to treat epilepsy)
  - certain medicines used in epilepsy, such as phenytoin, carbamazepine, primidone
  - certain antidepressants (tricyclic antidepressants)
  - medicines to treat tuberculosis, such as rifampicin and isoniazid
- loop diuretics
- probenecide (medicine used to treat high levels of uric acid in the blood and gout)
- zidovudine (also named AZT, a medicine used to treat HIV infections)
- chloramphenicol (an antibiotic used to treat infections)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment
- metoclopramide or domperidone (medicines to treat nausea and vomiting)
- cholestyramine (a medicine used to lower the cholesterol levels)
- coumarin anticoagulants to prevent blood clotting such as warfarin, phenprocoumon or acenocoumarol
- lamotrigine (a medicine used to treat epilepsy or mental diseases called bipolar disorders)
- salicylamide (a medicine to treat pain and inflammation)

**Taking [nationally completed name] with food and drink**

The use of paracetamol in patients who habitually consume alcohol (3 or more alcoholic beverages: beer, wine, liquor, daily) can cause liver damage.

**Pregnancy and breast-feeding**

Consult your doctor or pharmacist before using any medicine.

IMPORTANT FOR WOMEN

If you are pregnant or think you may be pregnant, talk to your doctor before taking this medicine. The consumption of medications during pregnancy can be dangerous for the embryo or fetus, and should be monitored by your doctor.

If necessary, [nationally completed name] can be used during pregnancy. You should use the lowest possible dose that reduces pain or fever and use it for the shortest possible time. Contact your doctor if the pain or fever does not subside or if you need to take the medication more often.

Consult your doctor or pharmacist before using any medicine.

Paracetamol passes into breast milk, so breastfeeding women should consult their doctor or pharmacist before taking this medicine.

**Driving and using machines**

[Nationally completed name] usually does not influence your ability to drive or use machines. However, if you experience side effects, such as dizziness, drowsiness, confusion or blurred vision, you should not drive or use machines.

**[Nationally completed name] contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take [nationally completed name]

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

[Non-prescription only]
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Always use the lowest effective dose to relieve your symptoms.

The recommended dose is:
Adults and adolescents aged 15 years and older (above 55 kg body weight)
Start with half a tablet (500 mg of paracetamol) and if needed 1 tablet (1000 mg); the maximum daily dose is 3 tablets (3000 mg of paracetamol).

After taking half a tablet of [nationally completed name], you should wait at least 4 hours before taking the next dose, even when the symptoms recur before.
After taking a whole tablet of [nationally completed name], you should wait at least 6 hours before taking the next dose, even when the symptoms recur before.

The daily dose should not exceed 60 mg paracetamol per kg body weight per day (up to 2 g per day) in the following situations:
- adults weighing less than 50 kg
- mild to severe hepatic insufficiency, Gilbert's Syndrome
- lack of total body water (dehydration)
- chronic malnutrition
- chronic alcoholism

Patients with liver diseases
Before taking this medicine they have to consult their doctor. They should take the amount of medication prescribed by their doctor with a minimum interval of 8 hours between each intake. They should not take more than 2 tablets of paracetamol in 24 hours, divided into 2 doses.

The use of high daily doses of paracetamol should be avoided for prolonged periods of time as it increases the risk of adverse effects such as liver damage.

Patients with kidney diseases
Before taking this medicine they have to consult their doctor. Take a maximum of 500 mg per dose. Due to the dose, 1 gram of paracetamol, the drug is not indicated for this group of patients.

The administration of this medicine is subject to the onset of pain or fever. As these disappear, treatment should be discontinued.
If the pain persists for more than 5 days, the fever for more than 3 days or the pain or fever worsens or other symptoms appear, you should stop treatment and consult your doctor.

**Method of administration**
For oral use.
Swallow the tablets with a sufficient amount of water or dissolve in a sufficient amount of water, stir well and drink up.

The tablet can be divided into equal doses.

**If you take more [nationally completed name] than you should**
You should consult your doctor or pharmacist immediately.
Symptoms of overdose may include: dizziness, vomiting, loss of appetite, yellowing of the skin and eyes (jaundice), and abdominal pain.
If you have ingested an overdose, you should go immediately to a medical center even if you do not notice the symptoms, since often these do not manifest until 3 days after the ingestion of the overdose, even in cases of severe poisoning.
Treatment of overdose is most effective if started within 4 hours of ingestion of the drug.
Patients on barbiturate treatment or chronic alcoholics may be more susceptible to the toxicity of a paracetamol overdose.
In case of overdose or accidental ingestion, go immediately to a medical center, indicating the medication and the amount ingested.

**If you forget to take [nationally completed name]**
Take the forgotten dose as soon as possible. However, ensure the minimum time period between doses (see above). Do not take a double dose to make up for a forgotten dose.

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.

Rare side effects that may occur (between 1 and 10 out of 10 000 people) are: discomfort, low blood pressure (hypotension), and increased levels of transaminases in the blood.

Very rare side effects that can occur (in less than 1 in 10 000 people) are: Kidney disease, cloudy urine, allergic dermatitis (rash), jaundice (yellowing of the skin), blood disorders (agranulocytosis, leukopenia, neutropenia, hemolytic anemia) and hypoglycemia (low blood sugar). Severe skin reactions have been reported very rarely.

Not known (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Paracetamol can damage the liver when taken in high doses or in prolonged treatments.

**Stop the treatment and contact your doctor immediately in case of serious allergic reactions (hypersensivity) to paracetamol with possible signs such as:** swelling of the face, lips, neck or throat (angioedema), shortness of breath (dyspnoea), sweating (sudation episodes), nausea, or low blood pressure, as well as shock (very rare: may affect up to 1 in 10 000 people).

**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 of the QRD template; to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store [nationally completed name]

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 blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 [nationally completed name] contains**
The active substance is paracetamol.
Each tablet contains 1000 mg paracetamol.
The other ingredients are pregelatinized starch (maize), povidone K-30 (E 1201), stearic acid (E 570), crospovidone (E 1202) and sodium starch glycolate (type A), purified water.

**What [nationally completed name] 1000 mg looks like and contents of the pack**
White, biconvex, oval shaped tablets debossed with a functional score line on one side and PC on the other side, with 21.0 ± 0.5 mm of length and 8.5±0.5 mm of width.

There are 8, 10, 16 (8x2) ,20 (10x2), 30 (10x3), 50 (10x5), 100 (10x10) tablets in a transparent PVC/PVDC-Aluminum blister pack.

Not all pack sizes may be marketed.

**Houder van de vergunning voor het in de handel brengen en fabrikant**

**Vergunninghouder**
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

**Fabrikant**
SAG Manufacturing S.L.U
Crta. N-I, Km 36
San Agustín de Guadalix
Madrid, 28750
Spanje

Galenicum Health, S.L.U.
Sant Gabriel 50
Esplugues de Llobregat
Barcelona, 08950
Spanje

**In het register ingeschreven onder:**
RVG 128940

**Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen**
Nederland: Paracetamol Sandoz 1000 mg, tabletten
Portugal: Paracetamol Sandoz

**Deze bijsluiter is voor het laatst goedgekeurd in januari 2025**