Bijsluiter: Informatie voor de patiënt

Paracetamol Sandoz® 500 mg, tabletten

paracetamol

[For medicines available only on 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 has 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.

[To be completed nationally]

What is in this leaflet
1. What [Nationally completed name] is and what it is used for
2. What you need to know before you take [Nationally completed name]
3. How to take [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Contents of the pack and other information

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] 500 mg>
[Nationally completed name] 500 mg is used for mild to moderate pain and fever in adults, adolescents and children aged 9 years and older.

<[Nationally completed name] 1000 mg>
[Nationally completed name] 1000 mg is used for mild to moderate pain associated with osteoarthritis of the hip and knee in adults and adolescents aged 15 years and older.

[Non-prescription:]
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.

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

Do not take [Nationally completed name]
- 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 [Nationally completed name] in case of:
- frequent use of large amounts of alcohol
- liver problems such as inflammation of the liver or reduced liver function
- Gilbert's syndrome (a rare hereditary metabolic disease with possible signs such as yellowing of the skin or whites of the eyes)
- kidney problems (moderate to severe renal impairment)
- 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
- asthmatic patients who are sensitive to acetylsalicylic acid

Consult your doctor if any of the above warnings applies to you, or has been in the past. You may need to avoid this medicine or need to reduce the dose of [Nationally completed name].

Warning: Taking higher doses than the recommended doses do not give better pain-relief, but cause the risk of serious liver damage. The maximum daily dose of paracetamol must therefore not be exceeded. Ask a doctor or pharmacist before concurrent use of other medicines also containing paracetamol. The symptoms of liver damage normally occur first after a couple of days. It is therefore important to seek medical advice immediately if you have taken more than recommended. See also section 3 "If you take more {[Nationally completed name]} than you should".

In case of high fever, signs of infection or if symptoms last longer (after 5 days for pain or after 3 days for fever) or get worse, you should contact a doctor.

Taking pain relieving medicines frequently for a long period of time can cause headaches or make them worse. You should not increase your dose of the pain relieving medicine, but contact your doctor for advice.

Effects of paracetamol on laboratory tests: For example, certain uric acid and blood sugar tests may be affected.

<[Nationally completed name] 500 mg>
Children
[Nationally completed name] 500 mg is not suitable for children below 9 years.

<[Nationally completed name] 1000 mg>
Children and adolescents
[Nationally completed name] 1000 mg is not suitable for children and adolescents below 15 years.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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
  - certain antidepressants (tricyclic antidepressants)
  - medicines to treat tuberculosis, such as rifampicin and isoniazid
- 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 (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used
- metoclopramide or domperidone (medicines to treat nausea and vomiting)
- colestyramine (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)

[Nationally completed name] with alcohol
Take care with the use of paracetamol when you frequently take large amounts of alcohol. You should not use more than 2 grams of paracetamol (4 tablets of 500 mg/ 2 tablets of 1000 mg) daily (see section 3. “How to take [Nationally completed name]”.
During treatment with [Nationally completed name], **do not drink alcoholic beverages.**

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, [Nationally completed name] can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Although paracetamol is excreted in breast milk in small amounts, no unwanted effects have been reported in breast-fed infants. [Nationally completed name] in recommended doses can be used during breast-feeding.

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.

This medicine contains paracetamol. Using too much paracetamol can seriously damage your liver. Do not use this medicine if you are taking other medicines containing paracetamol, whether or not on medical prescription, to treat pain, fever, cold symptoms and flu. Do not exceed the recommended dose.

<[Nationally completed name] 500 mg>
The recommended dose is:
Adults and adolescents aged 15 years and older (above 55 kg body weight)
Start with 1 tablet (500 mg of paracetamol) at a time, if necessary 2 tablets (1000 mg of paracetamol); maximum of 6 tablets (3000 mg of paracetamol) per 24 hours.

Adolescents between 12-15 years (40-55 kg of body weight)
1 tablet at a time, maximum of 4-6 tablets per 24 hours.

Children between 9-12 years (30-40 kg of body weight)
1 tablet at a time, maximum of 3-4 tablets per 24 hours.

After taking your dose of [Nationally completed name], you should wait at least 4 hours before taking the next dose, even when the symptoms recur before.

<[Nationally completed name] 1000 mg>
Adults and adolescents aged 15 years and older (above 55 kg body weight)
The recommended dose is:
Start with half a tablet (500 mg of paracetamol), and if needed 1 tablet (1000 mg); the maximum daily dose is 4 tablets (4000 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 moderate hepatic insufficiency, Gilbert's Syndrome
- lack of total body water (dehydration)
- chronic malnutrition
- chronic alcoholism

If pain persists for more than 5 days or fever for more than 3 days, or if symptoms worsen, stop taking [Nationally completed name] and talk to your doctor.
If prescribed by your doctor, he/she will tell you how long you may use this medicine.

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.

<[Nationally completed name] 1000 mg>
The tablet can be divided into equal doses.

If you take more [Nationally completed name] than you should
Immediately contact your doctor or a hospital emergency department if you have used more [Nationally completed name] than you should. Ingestion of a higher than recommended dose may cause nausea, vomiting and a lack of appetite. A single administration of several times the maximum daily dose can cause severe liver damage. Unconsciousness usually does not occur. However, even if no signs of overdose exist, you should seek immediate medical advice. Liver damage may become irreversible in case of delayed intervention.

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.

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).

The following other side effects may occur after the use of paracetamol:

Rare (may affect up to 1 in 1,000 people)
- certain blood disorders:
  - reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
  - unexplained haematoma (thrombocytopenic purpura)
  - reduction in white blood cells (leucopenia)
  - reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- severe reduction in number of white blood cells which makes infections more likely (agranulocytosis), after long-term treatment

- allergies (excluding angioedema)
- abnormal liver function, increase in liver enzymes seen in the blood, liver failure, liver necrosis, yellowing of the skin or whites of the eyes
- skin rash, itching, sweating, reddening, hives (urticaria)
- depression, confusion; seeing, feeling or hearing things that are not there (hallucinations)
- shaking, headache
- blurred vision
- swelling due to water retention (oedema)
- bleeding, stomach pain, diarrhoea, feeling sick, vomiting
- dizziness, generally feeling unwell, fever, drowsiness

Very rare (may affect up to 1 in 10,000 people)
- severe reduction in blood cells which can cause weakness, bruising or make infections more likely (pancytopenia)
- serious skin reactions
- generalised skin rash (exanthema)
- tightness due to cramps of the muscles of the airways (bronchospasm) in persons who are sensitive to acetylsalicylic acid or other non-stroidal anti-inflammatory drugs (NSAIDs, group of painkillers with anti-inflammatory and antipyretic effects).
- low blood sugar levels
- kidney impairment, inflammation in the kidneys (interstitial nephritis), cloudy urine (sterile pyuria), blood in the urine, inability to produce urine

Frequency not known (frequency cannot be estimated from the available data)
- serious skin reactions: acute generalized exanthematous pustulosis, toxic epidermal necrolysis, drug-induced dermatosis and Stevens-Johnson syndrome
- liver poisoning

Single amounts of 6 grams of paracetamol (in children above 140 mg/kg body weight), or long-term use of 3-4 grams of paracetamol daily, may cause liver damage.

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 500 mg paracetamol.
Each tablet contains 1000 mg paracetamol.
The other ingredients are povidone K-30 (E 1201), pregelatinized starch (maize), sodium starch glycolate (type A) and stearic acid (E 570).

500 mg tablets
What [Nationally completed name] 500 mg looks like and contents of the pack
White, caplet-shaped tablets, debossed with “500” on one side and plain on the other side (17.5 mm x 7.3 mm).

There are 10, 12, 16, 20, 24, 30, 50, 120 or 240 tablets in a blister pack or 100 tablets in a plastic bottle with a child resistant closure.

1000 mg tablets
What [Nationally completed name] 1000 mg looks like and contents of the pack
White to off-white, caplet-shaped tablets, debossed with scoreline between “10” and “00” on one side and scoreline between “PA” and “RA” on the other side (21.4 mm x 9.0 mm).

There are 8, 10, 16, 20, 30, 40, 60, 90 or 120 tablets in a blister pack or 100 tablets in a plastic bottle with a child resistant closure.

Not all pack sizes may be marketed.

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

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikant
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
RVG 111619

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen

Nederland:	Paracetamol Sandoz 500 mg, tabletten
Oostenrijk:	Paracetamol Sandoz 500 mg - tabletten
België:	Paracetamol Sandoz 500 mg Tabletten
Denemarken:	Paracetamol Sandoz
Finland:	Rolod
Hongarije:	Paracetamol Sandoz 500 mg tabletta
Italië:	PARACETAMOLO SANDOZ
Luxemburg:	Paracetamol Sandoz 500 mg Comprimés
Polen:	Paracetamol Sandoz

Portugal:	Paracetamol Sandoz
Roemenië	Paracetamol Sandoz 500 mg comprimate

Deze bijsluiter is voor het laatst goedgekeurd in mei 2022