

PARACETAMOL SANDOZ® PHARMA

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PARACETAMOL SANDOZ PHARMA?

PARACETAMOL SANDOZ PHARMA contains the active ingredient paracetamol. PARACETAMOL SANDOZ PHARMA is used to provide temporary relief of pain associated with headache, arthritis, muscular and neuralgic conditions, and to reduce fever.

For more information, see Section [1. Why am I using PARACETAMOL SANDOZ PHARMA?](#) in the full CMI.

2. What should I know before I use PARACETAMOL SANDOZ PHARMA?

Do not use if you have ever had an allergic reaction to paracetamol or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PARACETAMOL SANDOZ PHARMA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PARACETAMOL SANDOZ PHARMA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PARACETAMOL SANDOZ PHARMA?

- The label on the pack will tell you how to take your medicine and how often. If you are unsure about the directions ask your pharmacist or doctor.

More instructions can be found in Section [4. How do I use PARACETAMOL SANDOZ PHARMA?](#) in the full CMI.

5. What should I know while using PARACETAMOL SANDOZ PHARMA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using PARACETAMOL SANDOZ PHARMA.• Take PARACETAMOL SANDOZ PHARMA exactly as directed.
Things you should not do	<ul style="list-style-type: none">• Do not take more than the recommended dose unless your doctor tells you to• In children and adolescents, do not give PARACETAMOL SANDOZ PHARMA for more than 48 hours unless a doctor has told you to.• Adults and Children 12 years of age and over – do not take more than 8 tablets in 24 hours• Children (7-12 years of age) – do not take more than 4 tablets in 24 hours.
Drinking alcohol	<ul style="list-style-type: none">• Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C in a cool dry place away from moisture, heat and sunlight.• Keep your tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using PARACETAMOL SANDOZ PHARMA?](#) in the full CMI.

6. Are there any side effects?

- Less serious side effects include nausea and stomach pain.
- Tell your doctor or pharmacist immediately if you notice any of the following side effects: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin. They may be the signs of an allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PARACETAMOL SANDOZ® PHARMA

Active ingredient: *paracetamol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PARACETAMOL SANDOZ PHARMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PARACETAMOL SANDOZ PHARMA.**

Where to find information in this leaflet:

- [1. Why am I using PARACETAMOL SANDOZ PHARMA?](#)
- [2. What should I know before I use PARACETAMOL SANDOZ PHARMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PARACETAMOL SANDOZ PHARMA?](#)
- [5. What should I know while using PARACETAMOL SANDOZ PHARMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PARACETAMOL SANDOZ PHARMA?

PARACETAMOL SANDOZ PHARMA contains the active ingredient paracetamol.

PARACETAMOL SANDOZ PHARMA is used to provide temporary relief of pain associated with headache, arthritis, muscular and neuralgic conditions, and to reduce fever.

2. What should I know before I use PARACETAMOL SANDOZ PHARMA?

Warnings

Do not use PARACETAMOL SANDOZ PHARMA if:

- you are allergic to paracetamol, or any of the ingredients listed at the end of this leaflet. The symptoms of an allergic reaction may include:
 - shortness of breath wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skinAlways check the ingredients to make sure you can use this medicine.
- the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

Check with your doctor or pharmacist if you:

- have any other medical conditions
- have allergies to any ingredients listed under Product Details at the end of this leaflet
- have allergies to aspirin or any other NSAID medicine
- have liver or kidney problems
- have low glutathione reserves
- have Gilbert's syndrome
- have glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
- have acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- drink large quantities of alcohol
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

PARACETAMOL SANDOZ PHARMA may be used during pregnancy and if you are breastfeeding. However, it is recommended that non-drug therapy such as rest and massage be tried first. If PARACETAMOL SANDOZ PHARMA is needed during pregnancy, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with PARACETAMOL SANDOZ PHARMA and affect how it works.

These include:

- any medicines which thin the blood, for example warfarin
- medicines to treat epilepsy
- metoclopramide or domperidone, medicines used to control nausea and vomiting
- proprantheline, a drug used to treat stomach ulcers
- other pain relief medication
- alcohol and medicines containing alcohol (ethanol) eg, some cough syrups
- medicines used to treat depression
- medicines used to aid sleep

- chloramphenicol, an antibiotic used to treat ear and eye infections
- flucloxacillin, zidovudine and rifampicin, drugs used to treat infections
- probenecid, a drug used to treat high uric acid levels in the blood associated with gout
- colestyramine, a drug used to reduce blood cholesterol
- chelating resin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PARACETAMOL SANDOZ PHARMA.

4. How do I use PARACETAMOL SANDOZ PHARMA?

How much to take

The usual dose is:

Adults and Children 12 years of age and over:

- 1 to 2 tablets.
- This dosage may be repeated every 4 to 6 hours if necessary.
- You should not take more than 8 tablets in 24 hours.

Children (7-12 years of age):

- Half to 1 tablet.
- This dosage may be repeated every 4 to 6 hours if necessary.
- Children should not take more than 4 tablets in 24 hours.

PARACETAMOL SANDOZ PHARMA tablets are not recommended for children under 7 years.

Swallow tablets whole with a little water or other liquid.

When to take PARACETAMOL SANDOZ PHARMA

The label on the pack or bottle will tell you how to take your medicine and how often. If you are unsure about the directions ask your pharmacist or doctor.

Your doctor may ask you to take a different dose. If so, you should follow the doctor's instructions.

If you are unsure what dose to take, ask your pharmacist.

If you forget to take PARACETAMOL SANDOZ PHARMA

If you miss a dose, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much PARACETAMOL SANDOZ PHARMA

If you think that you have taken too much PARACETAMOL SANDOZ PHARMA, you may need urgent medical attention.

If you take too much PARACETAMOL SANDOZ PHARMA you may feel nauseous, dizzy or sweaty.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PARACETAMOL SANDOZ PHARMA?

Things you should do

- Take PARACETAMOL SANDOZ PHARMA exactly as directed.

Remind any doctor, dentist or pharmacist you visit that you are using PARACETAMOL SANDOZ PHARMA.

Things you should not do

- Do not take more than the recommended dose unless your doctor tells you to.

Adults:

- Do not take for more than a few days at a time unless your doctor tells you to.

Children and adolescents:

- Do not give PARACETAMOL SANDOZ PHARMA for more than 48 hours unless a doctor has told you to.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol.

Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack they will not keep well.
- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
General: <ul style="list-style-type: none">Nausea and vomitingSweating Gut related: <ul style="list-style-type: none">Stomach painIndigestion	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Skin related: <ul style="list-style-type: none">Skin rashesPainful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills Liver related: <ul style="list-style-type: none">Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine) Metabolism related: <ul style="list-style-type: none">Symptoms of rapid breathing, rapid heart rate and changes in consciousness caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due to low levels of a protein called glutathione) Allergic reaction: <ul style="list-style-type: none">Shortness of breathWheezing or difficulty breathingSwelling of the face, lips, tongue or other parts of the bodySevere blisters and bleeding in the lips, eyes, mouth, nose and genitalsRash, itching or hives on the skin	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What PARACETAMOL SANDOZ PHARMA contains

Active ingredient (main ingredient)	Paracetamol
Other ingredients (inactive ingredients)	Colloidal anhydrous silica Magnesium stearate Maize starch Povidone Purified talc Sodium lauryl sulfate Sodium metabisulfite Sodium starch glycollate
Potential allergens	Sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What PARACETAMOL SANDOZ PHARMA looks like

PARACETAMOL SANDOZ PHARMA – flat, round, scored, white tablet with bevelled edges, front face marking 'PARACETAMOL 500' with break line on the reverse. Pack sizes of 50 and 100 tablets. (Aust R 343019).

Who distributes PARACETAMOL SANDOZ PHARMA

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

This leaflet was prepared in September 2024.

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