

Parecoxib Sandoz® Powder for Solution for Injection

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 Parecoxib Sandoz?

Parecoxib Sandoz contains the active ingredient parecoxib. Parecoxib Sandoz is used for the prevention and treatment of pain. It can be used to relieve pain and reduce inflammation (swelling and soreness) which may occur after surgery.

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

2. What should I know before I use Parecoxib Sandoz?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. You must not be given Parecoxib Sandoz if you have had an attack of asthma, hives, itching, skin rash or a runny nose after taking aspirin or Non- Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to treat pain and inflammation), including other Coxib medicines.

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

3. What if I am taking other medicines?

Some medicines may interfere with Parecoxib Sandoz and affect how it works.

Your doctor and nurse need to know if you are taking any medicines used to treat high blood pressure or other heart problems. These include ACE inhibitors, angiotensin receptor antagonists, beta blockers and diuretics (also called fluid or water tablets).

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 Parecoxib Sandoz?

- Your doctor will decide how much Parecoxib Sandoz you need. The usual recommended dose is a single 40 mg injection.
- Your doctor may adjust the dosage you are given depending on your condition.

More information can be found in Section [4. How do I use Parecoxib Sandoz?](#) in the full CMI.

5. What should I know while using Parecoxib Sandoz?

Things you should not do	<ul style="list-style-type: none">• Do not take any other medication unless your doctor is aware of it.• You must not be given Parecoxib Sandoz if you are in the third trimester of your pregnancy or are breastfeeding.
Driving or using machines	<ul style="list-style-type: none">• This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor and nurse if you drink alcohol.

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

6. Are there any side effects?

Common side effects: changes in blood pressure, dizziness or light-headedness due to low blood pressure, back pain, ear ache, feeling numb, stomach upset.

Serious side effects: skin rash, blistering and bleeding in the lips, eyes, mouth, nose and genitals, a slow heartbeat, a severe or persistent headache, fever, stick neck, sensitivity to light and vomiting.

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.

Parecoxib Sandoz®

Active ingredient(s): *parecoxib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Parecoxib Sandoz. **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 Parecoxib Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Parecoxib Sandoz?

Parecoxib Sandoz contains the active ingredient parecoxib. Parecoxib Sandoz belongs to a group of medicines called Coxibs. These medicines work by relieving pain and inflammation.

Parecoxib Sandoz is used for the prevention and treatment of pain. It can be used to relieve pain and reduce inflammation (swelling and soreness) which may occur after surgery.

Although Parecoxib Sandoz can relieve the symptoms of pain and inflammation, it will not cure your condition.

Parecoxib Sandoz is an injection. Only a doctor or nurse can give the injection.

This medicine is not addictive.

2. What should I know before I use Parecoxib Sandoz?

Warnings

Do not use Parecoxib Sandoz if you have an allergy to:

- parecoxib sodium or valdecoxib
- any of the ingredients listed at the end of this leaflet
- sulphonamides, a group of medicines which include, for example, certain antibiotics (if you are not sure whether you are taking one of these medicines ask your doctor or nurse).

Some of the symptoms of an allergic reaction to Parecoxib Sandoz may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash

- swelling, blistering or peeling of the skin.

These symptoms may be severe if you are allergic to sulphonamides or to any of the ingredients listed at the end of this leaflet and you are given Parecoxib Sandoz.

Ask your doctor or nurse if any of this applies to you.

You must not be given Parecoxib Sandoz if you have had an attack of asthma, hives, itching, skin rash or a runny nose after taking aspirin or Non- Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to treat pain and inflammation), including other Coxib medicines.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or an NSAID.

If you are not sure if you are taking any of these medicines, ask your doctor or nurse.

If you are allergic to aspirin or NSAIDs, including other Coxib medicines and use Parecoxib Sandoz, these symptoms may be severe.

You must not be given Parecoxib Sandoz if you are about to undergo heart or blood vessel surgery.

You should not be given Parecoxib Sandoz if you have had any of the following medical conditions. Your doctor or nurse need to know if you have ever had:

- heart disease
- a heart attack
- a stroke
- severe liver problems.

You must not be given Parecoxib Sandoz if you are in the third trimester of your pregnancy or are breastfeeding.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor and nurse if you have any allergies to:

- any other medicines including aspirin or other NSAID medicines, including other Coxib medicines
- any other substances, such as foods, preservatives or dyes.

Your doctor and nurse need to know about all your medical conditions, especially if you have ever had any of the following:

- kidney or liver problems
- heart problems, heart surgery, heart failure, heart attack or other blood vessel disease
- stroke
- diabetes
- high cholesterol levels
- high blood pressure
- fluid retention or if you are receiving diuretic treatment

- dehydration
- asthma or other allergic conditions
- skin problems such as swelling, blistering, peeling, itching or redness that can occur with fever, chills, headache, joint pain or generally feeling unwell
- peptic ulcer i.e. stomach or duodenal ulcer.

Your doctor and nurse need to know if you currently have an infection.

If you are given Parecoxib Sandoz while you have an infection, it may hide some of the signs of an infection.

Your doctor and nurse need to know if you are a smoker or drink alcohol.

If you have not told your doctor and nurse about any of the above, tell them before you are given Parecoxib Sandoz.

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 nurse if you are pregnant or intend to become pregnant.

You should not be treated with Parecoxib Sandoz if you are in the third trimester of your pregnancy.

Treatment with Parecoxib Sandoz during the first two trimesters of your pregnancy is not recommended as it may affect your developing baby. It may also affect your labour. Your doctor will discuss with you the benefits and risks of treatment with Parecoxib Sandoz.

Related medicines, NSAIDs, have been associated with reversible infertility in some women.

Use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion and may affect your developing baby.

Treatment with NSAIDs in the second or third trimester of your pregnancy may cause kidney problems in your developing baby.

Your doctor will discuss with you the benefits and risks of using it.

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

You should not be given Parecoxib Sandoz if you are breastfeeding.

Parecoxib Sandoz passes into breast milk, therefore, breastfeeding should be discontinued during treatment with Parecoxib Sandoz.

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.

Your doctor and nurse need to know if you are taking any medicines used to treat high blood pressure or other heart problems. These include ACE inhibitors, angiotensin receptor antagonists, beta blockers and diuretics (also called fluid or water tablets).

These medicines can cause kidney problems if taken at the same time as you receive Parecoxib Sandoz.

Your doctor and nurse need to know if you are taking any of the following:

- aspirin, salicylates or other NSAID medicines used to treat pain, inflammation or swelling
- corticosteroids, medicines used to suppress the immune system or reduce inflammation
- selective serotonin reuptake inhibitors, medicines used for depression
- warfarin or similar medicines including Eliquis (apixaban), Xarelto (rivaroxaban), Pradaxa (dabigatran) or antiplatelet medicines that are used to prevent or stop blood clots from forming
- lithium, a medicine used to treat some types of depression
- some medicines used to treat diabetes
- methotrexate, a medicine used to treat arthritis and some cancers
- ciclosporin, a medicine used to suppress the immune system
- fluconazole and ketoconazole used to treat fungal infections.

Your doctor and nurse have more information on medicines to be careful with or avoid while using Parecoxib Sandoz.

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

4. How do I use Parecoxib Sandoz?

How much is given

- Your doctor will decide how much Parecoxib Sandoz you need. The usual recommended dose is a single 40 mg injection. Your doctor may adjust the dosage you are given depending on your condition.
- Parecoxib Sandoz will be given to you by your doctor. It is diluted and given by injection into a vein through an intravenous line or into a muscle.

Ask your doctor if you want more information about the dose of Parecoxib Sandoz and how it is given.

When to take Parecoxib Sandoz

- Your doctor will decide when you will need Parecoxib Sandoz.

If you receive too much Parecoxib Sandoz

As your doctor will supervise how much Parecoxib Sandoz you are given, you are unlikely to have an overdose.

If you are given too much Parecoxib Sandoz, you may feel tired, drowsy or sick, or you may be sick, have stomach pains or other abdominal problems.

If you think that you have been given too much Parecoxib Sandoz:

You should immediately:

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

5. What should I know while using Parecoxib Sandoz?

Things you should not do

- Do not take any other medication unless your doctor is aware of it.

Driving or using machines

Be careful driving or operating machinery after your surgery in case Parecoxib Sandoz has affected you.

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor and nurse if you drink alcohol.

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 about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Heart-related:</p> <ul style="list-style-type: none"> • changes in blood pressure • dizziness or light-headedness due to low blood pressure <p>Mouth and gum-related:</p> <ul style="list-style-type: none"> • sore throat • swollen and sore gums • inflammation and pain after a tooth extraction 	<p>Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking</p>

	Parecoxib Sandoz.
<p>Gut-related:</p> <ul style="list-style-type: none"> • stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps • constipation, diarrhoea, pain in the stomach, wind, bloating <p>Skin-related:</p> <ul style="list-style-type: none"> • feeling numb (your skin may lose sensitivity to pain and touch) • increased sweating <p>Mental or emotional-related:</p> <ul style="list-style-type: none"> • Trouble sleeping • Irritability, agitation <p>Others:</p> <ul style="list-style-type: none"> • back pain • ear ache • dizziness • passing less urine than normal 	

Serious side effects

Serious side effects	What to do
<p>Allergy-related:</p> <ul style="list-style-type: none"> • a skin rash, including hives, raised red, itchy spots • blistering and bleeding in the lips, eyes, mouth, nose and genitals • swelling, blistering or peeling of the skin, which may be accompanied by fever, chills, headache, sore throat, diarrhoea, aching joints and muscles • swollen glands e.g. under armpit or neck • any other signs of allergic reaction such as wheezing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing • swelling of lips and tongue <p>Heart-related:</p> <ul style="list-style-type: none"> • a slow heart beat • have irregular heartbeat, chest pain or discomfort, swollen or sore leg veins. <p>Head and neurology-related:</p> <ul style="list-style-type: none"> • a severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting • a dry mouth, feeling of thirst and needing to urinate more often 	<p>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.</p>

<ul style="list-style-type: none"> feeling faint or collapse, have shortness of breath, feel tired <p>Blood-related:</p> <ul style="list-style-type: none"> bleeding or bruising more easily than normal, reddish or purplish blotches under the skin any signs of anaemia, such as tiredness, being short of breath, and looking pale <p>Gut-related:</p> <ul style="list-style-type: none"> an unusual weight gain or loss of appetite unusual stomach sounds severe stomach or throat pain you are vomiting blood or having black sticky bowel motions <p>Musculoskeletal-related:</p> <ul style="list-style-type: none"> joint pain, muscle weakness <p>Skin-related:</p> <ul style="list-style-type: none"> any infection of, or discharge from, any wounds complications with skin healing after operations injection site pain or reaction yellowing of the skin or eyes (jaundice). 	
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Do not take this medicine if you are allergic to any of these ingredients.

What Parecoxib Sandoz looks like

Parecoxib Sandoz is supplied to the hospital in single-use glass vials, and requires dilution with normal saline before use.

Parecoxib Sandoz parecoxib (as sodium) 40 mg powder for injection vial (AUST R 380863)

10 vials per pack

Who distributes Parecoxib Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia

Tel 1800 726 369

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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 only available with a doctor's prescription.

What Parecoxib Sandoz contains

Active ingredient (main ingredient)	parecoxib (as parecoxib sodium)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Disodium hydrogen phosphate heptahydrate Phosphoric acid Sodium hydroxide