

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 being given PARECOXIB MEDSURGE?

PARECOXIB MEDSURGE contains the active ingredient parecoxib sodium. PARECOXIB MEDSURGE 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 MEDSURGE can relieve the symptoms of pain and inflammation, it will not cure your condition.

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

2. What should I know before I am given PARECOXIB MEDSURGE?

Do not use if you have ever had an allergic reaction to parecoxib sodium or valdecoxib 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.

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

3. What if I am taking other medicines?

Some medicines may interfere with PARECOXIB MEDSURGE 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 is PARECOXIB MEDSURGE given?

PARECOXIB MEDSURGE is an injection and will be given to you by your doctor or nurse.

This medicine is available only with a doctor's prescription.

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

5. What should I know while I am given PARECOXIB MEDSURGE?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using PARECOXIB MEDSURGE.
Things you should not do	Do not take any other medication unless your doctor is aware of it.
Driving or using machines	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	Your doctor and nurse need to know if you are a smoker or drink alcohol.

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

6. Are there any side effects?

Common side effects of PARECOXIB MEDSURGE include dizziness or lightheadedness, stomach upset, nausea, vomiting, heartburn, indigestion, cramps, constipation, diarrhoea, bloating, wind, sore throat and swollen gums. Serious side effects include signs of an allergic reaction including wheezing, swelling of face, lips, mouth throat and tongue leading to difficulty in swallowing or breathing.

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.

Active ingredient(s): *parecoxib (as sodium)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PARECOXIB MEDSURGE. **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 MEDSURGE.**

Where to find information in this leaflet:

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

1. Why am I being given PARECOXIB MEDSURGE?

PARECOXIB MEDSURGE contains the active ingredient parecoxib sodium. **PARECOXIB MEDSURGE** belongs to a group of medicines called Coxibs. These medicines work by relieving pain and inflammation.

PARECOXIB MEDSURGE 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 MEDSURGE** can relieve the symptoms of pain and inflammation, it will not cure your condition.

2. What should I know before I am given PARECOXIB MEDSURGE?

Warnings

Do not use PARECOXIB MEDSURGE 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
- You are about to undergo heart or blood vessel surgery have had any of the following medical conditions:
 - heart disease
 - a heart attack
 - a stroke
 - severe liver problems
- You should not be treated with **PARECOXIB MEDSURGE** if you are in the third trimester of your pregnancy or are breastfeeding
- You are allergic to

- parecoxib or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Valdecoxib
- 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).

Check with your doctor if you:

Have any of the following medical conditions:

- 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 with symptoms such as swelling, blistering, peeling, itching, reddening or some other abnormality
- peptic ulcer i.e. stomach or duodenal ulcer.

If you 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 them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

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

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

Use of Parecoxib during pregnancy is not recommended as it may affect your developing baby. It may also affect labour.

Use of 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 if you are breastfeeding or intend to breastfeed.

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

Infection

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

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

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
- all prescription medicines
- all medicine bought over-the counter from a pharmacy or supermarket
- all complementary and alternative therapies
- any supplements or herbal remedies bought from a health food shop.

Some medicines may interfere with PARECOXIB MEDSURGE and affect how it works.

- 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 MEDSURGE.
- 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 apixaban, rivaroxaban, 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.
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- fluconazole and ketoconazole used to treat fungal infections.

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 MEDSURGE.

4. How is PARECOXIB MEDSURGE given?

How much is given

Your doctor will decide how much PARECOXIB MEDSURGE 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 MEDSURGE will be given to you by your doctor or nurse. It is diluted and given by injection into a vein through an intravenous line or into a muscle.

When is PARECOXIB MEDSURGE given?

PARECOXIB MEDSURGE should be used to relieve pain and reduce inflammation (swelling and soreness) which may occur after surgery.

This medicine is available only with a doctor's prescription. This medicine is not addictive.

If you use too much PARECOXIB MEDSURGE

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

If you are given too much Parecoxib, 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 used too much PARECOXIB MEDSURGE, you may need urgent medical attention.

You should immediately:

phone the Poisons Information Centre (**by calling 0800 POISON or 0800 764 766**), 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 PARECOXIB MEDSURGE?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using PARECOXIB MEDSURGE.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PARECOXIB MEDSURGE affects 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.

PARECOXIB MEDSURGE

Drinking alcohol

Tell your doctor if you drink alcohol.

This medicine may cause dizziness or light-headedness in some people.

Looking after your medicine

Parecoxib Medsurge to be Stored in the pharmacy at below 30°C. Protect from light.

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
• changes in blood pressure • dizziness or light-headedness due to low blood pressure • back pain • earache • feeling numb (your skin may lose sensitivity to pain and touch) • stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps • Constipation, diarrhoea, pain in the stomach, wind, bloating • Dizziness • sore throat • swollen and sore gums • increased sweating • passing less urine than normal • inflammation and pain after a tooth extraction • trouble sleeping • irritability, agitation	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• 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	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

- any other signs of allergic reaction such as wheezing, swelling of lips and tongue or throat which may cause difficulty in swallowing or breathing
- unusual stomach sounds
- loss of appetite
- severe stomach or throat pain
- a dry mouth, feeling of thirst and needing to urinate more often
- 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)
- feeling faint or collapse, have shortness of breath, feel tired
- have irregular heartbeat chest pain or discomfort, swollen or sore leg veins
- 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
- a severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting
- unusual weight gain
- joint pain
- muscle weakness
- vomiting blood or having black sticky bowel motions
- feeling faint or collapse, have shortness of breath, feel tired

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 (Australia) or the Centre for Adverse Reactions Monitoring (CARM) within the New Zealand Pharmacovigilance Centre : <https://pophealth.my.site.com/carmreportnz/s/> (New Zealand). 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 MEDSURGE contains

Active ingredient (main ingredient)	Parecoxib (as sodium)
Other ingredients (inactive ingredients)	Dibasic sodium phosphate heptahydrate phosphoric acid sodium hydroxide
Potential allergens	Parecoxib does not contain gluten, dyes or preservatives.

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

What PARECOXIB MEDSURGE looks like

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

It is a white to off-white powder.

Parecoxib Medsurge may also be supplied along with normal saline in glass ampoules for dilution.

When Parecoxib Medsurge diluted, it is a clear and colourless solution.

Who distributes PARECOXIB MEDSURGE

Medsurge Pharma Limited

PO Box 331054

Takapuna

Auckland 0622

Telephone: 0800 788 261

Website: www.medsurgehc.com.

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