

Package leaflet: Information for the patient

Parecoxib WB powder for solution for Injection 40mg/vial Parecoxib sodium

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Parecoxib is and what it is used for
2. What you need to know before you are given Parecoxib
3. How Parecoxib is given
4. Possible side effects
5. How to store Parecoxib
6. Contents of the pack and other information

1. What Parecoxib is and what it is used for

Parecoxib belongs to a family of medicines called COX-2 inhibitors (cyclo-oxygenase-2 inhibitors). This medicine works by lowering the amount of prostaglandins in the body (prostaglandins are substances that can cause pain and swelling).

Parecoxib is used for the short-term treatment of pain in adults after an operation.

2. What you need to know before you are given Parecoxib

You must not be given Parecoxib:

- if you are allergic to parecoxib or any of the other ingredients of this medicine (listed in section 6);
- if you have had a serious allergic reaction (especially a serious skin reaction) to any medicines;
- if you have had an allergic reaction to a group of medicines called “sulfonamides” (e.g. some antibiotics used to treat infections);
- if you currently have a gastric or intestinal ulcer or bleeding in the stomach or gut;
- if you have had an allergic reaction to acetylsalicylic acid (aspirin) or to other NSAIDs (e.g. ibuprofen) or to COX-2 inhibitors. Reactions might include wheezing (bronchospasm), badly blocked nose, itchy skin, rash or swelling of the face, lips or tongue, other allergic reactions or nasal polyps after taking these medicines.
- if you are more than 6 months pregnant;
- if you are breast-feeding;
- if you have severe liver disease;
- if you have inflammation of the intestines (ulcerative colitis or Crohn’s disease);
- if you have heart failure;
- if you are about to have heart surgery or surgery on your arteries (including any coronary artery procedure);

- if you have established heart disease and/or cerebrovascular disease, e.g., if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages;
- if you have or have had problems with your blood circulation (peripheral arterial disease).

If any of these apply to you, **tell your doctor or nurse immediately**, as you must not be given the injection.

Warnings and precautions

You must not be given Parecoxib if you currently have a gastric or intestinal ulcer or gastrointestinal bleeding, or if you suffer from severe liver disease.

Talk to your doctor or nurse before you are given Parecoxib:

- if you have previously had an ulcer, bleeding or perforation of the gastrointestinal tract;
- if you are taking acetylsalicylic acid (aspirin) or other NSAIDs (e.g. ibuprofen);
- if you smoke or drink alcohol;
- if you have diabetes;
- if you have angina (chest pain), blood clots, high blood pressure or raised cholesterol;
- if you are taking anti-platelet therapies (e.g. acetylsalicylic acid);
- if you have fluid retention (oedema);
- if you have liver or kidney disease;
- if you are dehydrated – this may happen if you have had diarrhoea or have been vomiting (being sick) or unable to drink fluids;
- if you have an infection, as it may hide a fever (which is a sign of infection);
- if you use medicines to reduce blood clotting (e.g. warfarin/warfarin like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban, dabigatran, and rivaroxaban);
- if you use medicines called corticosteroids (e.g. prednisone);
- if you use a class of medicines used to treat depression called selective serotonin re-uptake inhibitors (e.g. sertraline).

Parecoxib can lead to an increase in blood pressure or worsening of existing high blood pressure which may result in an increase in side-effects associated with heart conditions. Your doctor may want to monitor your blood pressure during treatment with this medicine.

Children and adolescents

Children and adolescents under the age of 18 must not be given Parecoxib.

Other medicines and Parecoxib

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Medicines can sometimes interfere with each other. Your doctor may reduce the dose of Parecoxib or other medicines, or you may need to take a different medicine. It's especially important to mention:

- Acetylsalicylic acid (aspirin) or other anti-inflammatory medicines;
- Fluconazole (used for fungal infections);
- Medicines for high blood pressure and heart conditions (ACE inhibitors, Angiotensin-II inhibitors, beta-blockers and diuretics);
- Ciclosporin or Tacrolimus (used after transplants);
- Warfarin or other warfarin like medicines (used to prevent blood clots) including newer medicines like apixaban, dabigatran, and rivaroxaban;
- Lithium (used to treat depression);
- Rifampicin (used for bacterial infections);
- Antiarrhythmics (used to treat an irregular heartbeat);
- Phenytoin or Carbamazepine (used for epilepsy);
- Methotrexate (used for rheumatoid arthritis, psoriasis and cancer);

- Diazepam (used for sedation and anxiety);
- Omeprazole (used for treating ulcers).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before you are given this medicine.

Pregnancy

If you are pregnant or trying to become pregnant, tell your doctor. Parecoxib is not recommended in the first 6 months of pregnancy and you must not receive this medicine in the last three months of pregnancy.

Breast-feeding

If you are breast-feeding, you must not receive this medicine, as a small amount of Parecoxib will be transferred to your breast milk.

Fertility

Medicines like Parecoxib may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

If the injection makes you feel dizzy or tired, do not drive or use machines until you feel better again.

Parecoxib contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per dose, that is to say essentially 'sodium-free'.

3. How Parecoxib is given

Parecoxib will be given to you by a doctor or nurse. They will dissolve the powder before giving you the injection, and will inject the solution into a vein or a muscle. The injection may be given rapidly and directly into a vein or into an existing intravenous line (a thin tube running into a vein), or it can be given slowly and deeply into a muscle. You will only be given Parecoxib for short periods, and only for pain relief.

The usual dose to start with is 40 mg.

You may be given another dose – either 20 mg or 40 mg – 6 to 12 hours after the first one.

You will not be given more than 60 mg in 24 hours.

Some people may be given lower doses:

- People with liver problems
- People with severe kidney problems
- Patients over 65 who weigh less than 50 kg
- People taking Fluconazole

If Parecoxib is used with strong pain killers (called opioid analgesics) such as morphine, the dose of Parecoxib will be the same as explained above.

If you are given more Parecoxib than you should you may experience side-effects that have been reported with recommended doses.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You need to stop receiving Parecoxib and tell your doctor immediately:

- if you develop a rash or ulceration in any part of your body (e.g. skin, mouth, eyes, face, lips or tongue), or develop any other signs of an allergic reaction such as skin rash, swelling of the face, lips or tongue which may cause wheezing, difficulty breathing, or swallowing – this occurs rarely);
- if you have blistering or peeling of the skin - this occurs rarely;

The onset of skin reactions can occur at any time but most often occur in the first month of treatment; the reported rate of these events appears to be greater for valdecoxib, a medicine related to parecoxib, as compared to other COX-2 inhibitors.

- if you have jaundice (your skin or the whites of your eyes appear yellow);
- if you have any signs of bleeding in the stomach or intestine, such as passing a black or blood-stained bowel movement or vomiting blood.

Other possible side effects

Very common (may affect more than 1 in 10 people)

- Nausea (feeling sick)

Common (may affect up to 1 in 10 people)

- Change in your blood pressure (high or low blood pressure)
- Back pain
- Swelling of ankles, legs and feet (fluid retention)
- Feeling numb – the skin may lose sensitivity to pain and touch
- Vomiting, stomach ache, indigestion, constipation, bloating and wind
- Tests may show abnormal kidney function
- Agitation, difficulty sleeping
- Dizziness
- Risk of anaemia - changes in red blood cells after an operation that may cause fatigue and breathlessness
- Sore throat or difficulty breathing (shortness of breath)
- Itchy skin
- Passing less urine than usual
- Dry socket (inflammation and pain after a tooth extraction)
- Increased sweating
- Low levels of potassium in blood test results

Uncommon (may affect up to 1 in 100 people)

- Heart attack
- Risk of cerebrovascular disease, e.g., stroke or transient ischaemic attack (transient reduced blood flow to the brain)/mini-stroke or angina, or blockages to blood vessels to the heart or brain
- Blood clot in the lungs
- Worsening of high blood pressure
- Ulcers in the digestive system, chronic stomach acid reflux
- The heart may beat more slowly
- Low blood pressure on standing
- Blood tests may show abnormal liver function
- Bruising easily due to a low blood platelet count
- Infection of the surgical wounds, abnormal discharge from surgical wounds
- Skin discolouration or bruising
- Complications with skin healing after operations

- High sugar levels in blood tests
- Pain or reaction at the injection site
- Rash, or raised itchy rash (hives)
- Anorexia (loss of appetite)
- Joint pain
- High levels of blood enzymes in blood tests that indicate injury or stress to the heart, the brain, or muscle tissue
- Dry mouth
- Muscle weakness
- Ear ache
- Unusual abdominal sounds

Rare (may affect up to 1 in 1,000 people)

- Rash or ulceration in any part of the body (e.g. skin, mouth, eyes, face, lips or tongue), or any other signs of allergic reactions such as skin rash, swelling of the face, lips and tongue, wheezing, difficulty breathing or swallowing (potentially fatal)
- Swelling, blistering or peeling of the skin
- Acute kidney failure
- Inflammation of the liver (hepatitis)
- Inflammation of the gullet (oesophagitis)
- Inflammation of the pancreas (pancreatitis - can lead to stomach pain)

Not known (frequency cannot be estimated from the available data)

- Collapse due to severe low blood pressure
- Heart failure
- Kidney failure
- Racing or irregularity of the heartbeat
- Breathlessness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Parecoxib

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

Please store this medicine at 30°C or below prior to reconstitution.

It is recommended that Parecoxib is used as soon as possible after it is mixed with solvent, although it may be stored up to 24 hours at 30°C if the instructions at the end of the leaflet are strictly followed.

The injection solution should be a clear colourless liquid. If there are particles in the injection solution or if either the powder or solution is discoloured, the solution must not be used.

Your doctor or the hospital will normally store Parecoxib and they are responsible for the quality of the product when it has been opened if it is not used immediately. They are also responsible for disposing of any unused Parecoxib correctly.

6. Contents of the pack and other information

What Parecoxib contains

- The active substance is parecoxib (as parecoxib sodium). Each vial contains 40 mg parecoxib, as 42.36 mg parecoxib sodium. When reconstituted with 2 ml solvent, it provides 20 mg/ml of parecoxib. When reconstituted in sodium chloride 9 mg/ml (0.9%) solution, it contains approximately 0.44 mEq of sodium per vial.
- The other ingredients are: disodium phosphate, phosphoric acid and/or sodium hydroxide (for pH adjustment).

What Parecoxib looks like and contents of the pack

Parecoxib is available as a white or almost white cake or powder.

The powder is contained in clear colourless glass vials (5 ml) with a coated butyl stopper, sealed with a blue flip-off cap on the aluminium overseal.

Each pack contains 10 vials.

Marketing Authorisation Holder/Product Registrant

Alma-A Pte. Ltd.,
1 Magazine Road #04-11, Central Mall Singapore 059567

Manufacturer

Wanbang Biopharmaceuticals
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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