Patient Information Leaflet

SCHEDULING STATUS: S3

PARECOXIB 40 MACLEODS; 40 mg IV/IM powder for solution for injection

Parecoxib

Sugar free

Read all of this leaflet carefully before you are given PARECOXIB 40 MACLEODS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask you doctor, pharmacist, nurse or other healthcare provider.
- PARECOXIB 40 MACLEODS has been prescribed for you personally.

What is in this leaflet

1. What PARECOXIB 40 MACLEODS is and what it is used for

2. What you need to know before you are given PARECOXIB 40 MACLEODS

3. How PARECOXIB 40 MACLEODS is given to you

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1. What PARECOXIB 40 MACLEODS is and what it is used for

PARECOXIB 40 MACLEODS contains the active ingredient parecoxib and belongs to a group of medicines called specific cyclooxygenase-2 (COX-2) inhibitors. Parecoxib works by reducing the production of prostaglandins in the body (prostaglandins are substances that can cause pain and swelling).

PARECOXIB 40 MACLEODS is used for the short-term treatment of pain after surgery in adults. The injection is given to you by a doctor or nurse, usually in a hospital or clinic, after an operation.

2. What you need to know before you are given PARECOXIB 40 MACLEODS

PARECOXIB 40 MACLEODS should not be given to you:

- If you are hypersensitive (allergic) to parecoxib or to any of the ingredients in PARECOXIB 40 MACLEODS (listed in section 6)
- If you have had an allergic reaction to a group of medicines called “sulphonamides” (an antibiotic used to treat infections)
- If you have had nasal polyps or severe nasal congestion, or an allergic reaction such as an itchy skin rash, swelling, or wheezing after taking aspirin or another anti-inflammatory medicine, including other cyclooxygenase-2 inhibitors
- If you have severe liver or kidney disease
- If you are about to have coronary artery bypass graft surgery
- If you have severe heart failure, high blood pressure or if you have had a stroke
- If you have or previously have had a stomach or duodenal ulcer, or bleeding in the stomach
- If you use lithium or digoxin
- If you have porphyria (a hereditary metabolic defect)
- If you are pregnant, or it is possible that you could become pregnant
- If you are breastfeeding your baby
- If you are younger than 18 years of age

Warnings and precautions

Take special care with PARECOXIB 40 MACLEODS. Tell your doctor or healthcare provider before being given the injection:

- If you have or have had heart disease or high blood pressure. Non-steroidal anti-inflammatory drug (NSAIDs) as in PARECOXIB 40 MACLEODS may increase the risk of harmful cardiovascular events including heart attack, stroke, heart failure, and atrial fibrillation. Your doctor may want to monitor your blood pressure.
- If you smoke
- If you have diabetes
- If you have high cholesterol
- If you have had an ulcer, bleeding, or hole or tear in your stomach and/or intestine.
- If a part of your stomach squeezes into the chest through the diaphragm (hiatus hernia) or you suffer from gastro-oesophageal reflux.
- If you experience a serious skin reaction (skin rash, mucosal lesions or any other sign of hypersensitivity), you need to tell your doctor or nurse immediately. PARECOXIB 40 MACLEODS may increase the risk of harmful skin reactions (see section 4 'Possible side effects')
- If you have kidney or liver disease
- If you have fluid retention (oedema i.e. swelling of feet and ankles)
- If you could be dehydrated, for example by the use of diuretics, or due to vomiting and diarrhoea
- If you are taking any other types of painkillers or anti-inflammatory medicines (NSAIDs)
- If you are taking warfarin or other blood thinning medicines
- If you have an infection, as it may hide fever and delay the detection of the cause of the fever.

Other medicines and PARECOXIB 40 MACLEODS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Before your first PARECOXIB 40 MACLEODS injection is administered to you, make sure your doctor knows if you are taking the following medicines.

- Lithium (used to treat depression) (see 'PARECOXIB 40 MACLEODS should not be given to you')
- Digoxin (used for heart failure) (see 'PARECOXIB 40 MACLEODS must not be given to you')
- Fluconazole or ketoconazole (used to treat fungal infections). These medicines cause increased levels of PARECOXIB 40 MACLEODS in your blood. Your doctor may decrease your dose of PARECOXIB 40 MACLEODS
- Aspirin
- Warfarin (used to prevent blood from clotting). PARECOXIB 40 MACLEODS may increase the risk for bleeding complications. Your doctor may want to test your blood more frequently.
- Angiotensin-converting enzyme (ACE) inhibitors (used for high blood pressure and heart failure). PARECOXIB 40 MACLEODS may decrease the antihypertensive effect of ACE inhibitors (some examples are perindopril, captopril). Your doctor may want to monitor your blood pressure closely and adjust your treatment if necessary.

  PARECOXIB 40 MACLEODS in combination with ACE inhibitors or angiotensin-II antagonists (some examples are valsartan, telmisartan) may affect how your kidneys work and may increase the risk of kidney failure.
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants). PARECOXIB 40 MACLEODS in combination with these products may affect how well your kidneys are working. Your doctor may want to monitor your renal function.
- Diuretics (used to treat fluid retention)
- Other medicines to treat cough, diabetes, pain and rheumatoid arthritis

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby. Please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

If you are pregnant, or trying to become pregnant, you must not receive PARECOXIB 40 MACLEODS. The mother, unborn or newborn baby may be harmed: The unborn baby might suffer from kidney dysfunction and subsequent reduction of amniotic fluid volume, or heart problems and possible high blood pressure in the lungs if PARECOXIB 40 MACLEODS is used during the last 3 months of pregnancy. At the end of pregnancy, the mother and neonate might suffer from prolongated bleeding time, or the onset of labour may be delayed and its duration increased.

If you are breastfeeding, you must not receive PARECOXIB 40 MACLEODS, as a small amount of PARECOXIB 40 MACLEODS can be transferred to the breastmilk. It is best to stop breastfeeding altogether before you are given PARECOXIB 40 MACLEODS.

NSAIDs, including PARECOXIB 40 MACLEODS, can make it more difficult to get pregnant. You must tell your doctor if you are planning to become pregnant or if you are having problems becoming pregnant.

Driving and using machines

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

It is not always possible to predict to what extent PARECOXIB 40 MACLEODS may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which PARECOXIB 40 MACLEODS affects you.

PARECOXIB 40 MACLEODS contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per mL and is, so to say, essentially 'sodium-free'.

3. How PARECOXIB 40 MACLEODS is given to you

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself PARECOXIB 40 MACLEODS. It will be given to you by a person who is qualified to do so.

The usual dose to start with is 40 mg. You may be given another dose 6 – 12 hours after the first one. You will not be given more than 80 mg in 24 hours.

Some people may be given lower doses if they have liver problems, or if they are elderly patients weighing less than 50 kg.

Opioid analgesics can be used together with PARECOXIB 40 MACLEODS as described above for the relief of pain. PARECOXIB 40 MACLEODS should not be used for longer than 48 hours in patients following hip replacement surgery.

If you have the impression that the effect of PARECOXIB 40 MACLEODS is too strong or too weak, tell your doctor.

If you receive more PARECOXIB 40 MACLEODS than you should

Since a healthcare provider will administer PARECOXIB 40 MACLEODS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of PARECOXIB 40 MACLEODS

Since a healthcare provider will administer PARECOXIB 40 MACLEODS, it is unlikely that the dose will be missed.

4. Possible side effects

PARECOXIB 40 MACLEODS can have side effects.

Not all side effects reported for PARECOXIB 40 MACLEODS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PARECOXIB 40 MACLEODS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving PARECOXIB 40 MACLEODS and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash, itching, warm red skin, blistering or peeling of the skin.
- If you have cardiac symptoms such as shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm, a weak pulse, low blood pressure, sweating, changes in the way your heart beats, for example, if you notice it beating faster.
- If you have signs of stomach or intestinal bleeding, such as black or bloody vomiting, stool or blood.
- If you have shortness of breath, chest pain and coughing up blood-streaked sputum, you may have a blockage in the lungs caused by blood clots.

These are all very serious side effects. If you have them, you may have had a serious reaction to PARECOXIB 40 MACLEODS. You may need urgent medical attention or further hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Dry socket (a complication of wound healing following tooth extraction)
- Post-operative anaemia (lack of red blood cells, seen with laboratory test)

- Lower than normal potassium level in your blood
- Problems sleeping
- Numbness or loss of sensitivity to touch or sensation
- Dizziness
- Blood pressure may become lower (you may feel dizzy, have blurred vision)
- Difficulty breathing
- Nausea and vomiting
- Stomach ache, indigestion or constipation
- Itchy skin or rash
- Increased sweating
- Urinating less than usual
- Ankles, legs or feet may swell (fluid retention)

Less frequent side effects

- Abnormal discharge from surgical wounds
- Surgical wounds may become infected
- Sore throat (pharyngitis)
- Bruising (or low blood platelet count)
- High blood sugar
- Anorexia (loss of appetite)
- Feeling agitated
- Risk of stroke or blockage to blood vessels to the heart
- Earache
- Heart attack or heart failure
- Slower, faster or irregular heartbeat and palpitations
- Blood pressure may become higher than usual
- Low blood pressure on standing (you may feel lightheaded and dizzy)
- Dry mouth

- Inflammation of the lining of the gullet (oesophagus)
- Stomach acid reflux
- Unusual abdominal sounds
- Inflammation of the pancreas (can lead to stomach pain)
- Swelling of the area around the mouth
- Flatulence (bloating and wind)
- Bruising of the skin
- Rash, or raised itchy rash (hives)
- Joint pain
- Back pain
- Injection site pain or injection site reactions
- Lack of energy
- Acute kidney failure

* Laboratory tests may show:

- Increased blood creatinine shown in laboratory tests (may indicate an effect on how well your kidneys work)
- Increased creatine phosphokinase (a test that may show that your heart muscle or muscles are affected)
- Abnormal liver or kidney function

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

By reporting side effects, you can help provide more information on the safety of PARECOXIB 40 MACLEODS.

5. How to store PARECOXIB 40 MACLEODS

Store all medicines out of reach of children.

PARECOXIB 40 MACLEODS should be stored at or below 30°C in the outer container and protected from light.

PARECOXIB 40 MACLEODS should not be used after the expiry date stated on the label.

Your doctor or hospital will normally store PARECOXIB 40 MACLEODS.

Your doctor or nurse will use PARECOXIB 40 MACLEODS as soon as possible after it is mixed with the solvent.

They are also responsible for the proper disposal of any unused PARECOXIB 40 MACLEODS.

6. Contents of the pack and other information

What PARECOXIB 40 MACLEODS contains

- The active substance is parecoxib.

  Each 5 mL vial contains 40 mg parecoxib (present as 42,36 mg lyophilised parecoxib sodium). After reconstitution the final concentration of parecoxib is 20 mg/mL.
- The other ingredients are dibasic sodium phosphate heptahydrate. Phosphoric acid and/or sodium hydroxide may have been added for pH adjustment.

What PARECOXIB 40 MACLEODS looks like and contents of the pack

PARECOXIB 40 MACLEODS powder is a white to off-white lyophilised dry cake or powder in a single use glass vial. When mixed, the solution is clear and colourless.

PARECOXIB 40 MACLEODS lyophilised powder is packed in a 5 mL colourless Type I single use glass vial, sealed with a chlorinated butyl rubber stopper coated with ETFE (ethylene tetrafluoroethylene) with an aluminium-plastic cap.

Pack sizes available: sets of either 1, 3, 5 or 10 vials containing parecoxib 40 mg (as parecoxib sodium) packed into an outer carton.

Not all pack sizes may be marketed.

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Access to the corresponding Professional Information

For professional information, please refer to the SAHPRA Repository of Professional Information and Patient Information Leaflets: https://www.sahpra.org.za/pi-pil-repository/.