PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PERICOB 40 powder for solution for injection

Parecoxib

Sugar free

Read all of this leaflet carefully before you receive PERICOB 40

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PERICOB 40 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PERICOB 40 is and what it is used for

PERICOB 40 contains the active substance parecoxib. It is one of a family of medicines called COX-2 inhibitors (this is short for cyclo-oxygenase-2 inhibitors). Pain and swelling are sometimes caused by substances in the body called prostaglandins. PERICOB 40 works by lowering the amount of these prostaglandins. PERICOB 40 is used for the short-term treatment of pain in adults after an operation.

2. What you need to know before you receive PERICOB 40

PERICOB 40 should not be administered to you:

- if you are hypersensitive (allergic) parecoxib or any of the other ingredients of PERICOB 40 (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 pregnant
- if you are breastfeeding.
- 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 you are younger than 18 years old.

Warnings and precautions

Take special care with PERICOB 40: Tell your doctor or health care provider before receiving PERICOB 40:

If you are planning to fall pregnant or if you are pregnant from week 1 to the end of week 12 (first trimester). Receiving PERICOB 40 at this stage of your pregnancy can result in the loss of your unborn baby, harm the heart and abdomen (belly) of your unborn baby.

If you are pregnant from week 13 to the end of the pregnancy (second and third trimester). Receiving PERICOB 40 at this stage of your pregnancy can harm the heart and kidneys of your unborn baby, which can decrease the amount of the liquid (amniotic fluid) that surrounds and protect your unborn baby during pregnancy. Complications can occur with low levels of amniotic fluid. Receiving PERICOB 40 at the end of pregnancy can also expose the mother and the unborn baby to too much bleeding and can prevent the tightening of the muscles of the uterus, causing a delay in the delivery of the baby.

Tell your doctor or health care provider as soon as possible if you start

experiencing any of the following reactions after receiving PERICOB 40.

- Fever
- Skin reactions, such as for example rash and swelling of the face
- Swelling of lymph nodes, for example swelling in the neck, armpits, and the groin
- Liver disease
- Kidney disease
- Bleeding or other blood disorders
- Chest pain, abnormal heartbeat, and shortness of breath
- Weak, painful, or aching muscles

These are all very serious, life-threatening side effects that can be due to a severe adverse drug reaction known as Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS), which has been reported in patients receiving medicines such as PERICOB 40.

PERICOB 40 may increase the incidence of cardiovascular events, cerebrovascular events, gastrointestinal events, or skin reactions which may be fatal.

Talk to your doctor or nurse before receiving PERICOB 40:

- 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, 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 disease.
- If you have 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 use medicines to reduce blood clotting (e.g. warfarin/warfarin like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban, dabigatran, and rivaroxaban).

PERICOB 40 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 PERICOB 40.

Children and adolescents

Children and adolescents under the age of 18 should not be given PERICOB 40.

Other medicines and PERICOB 40

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

It is especially important to mention:

- Acetylsalicylic acid (aspirin) or other anti-inflammatory medicines
- Fluconazole – used for fungal infections
- ACE inhibitors, Angiotensin-II inhibitors, beta blockers and diuretics – used for high blood pressure and heart conditions
- 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
- Anti-dysrhythmics – used to treat an irregular heartbeat
- Phenytoin or carbamazepine – used for epilepsy
- Methotrexate – used for rheumatoid arthritis and cancer
- Diazepam – used for sedation and anxiety
- Omeprazole – used for treating ulcers

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 health care provider for advice before receiving PERICOB 40.

Pregnancy

If you are pregnant or trying to become pregnant, tell your doctor. PERICOB 40 should not be given during pregnancy.

If you are pregnant from week 1 to the end of week 12 (first trimester): Receiving PERICOB 40 at this stage of your pregnancy can result in the loss of your unborn baby, harm the heart and abdomen (belly) of your unborn baby.

If you are pregnant from week 13 to the end of the pregnancy (second and third trimester): Receiving PERICOB 40 at this stage of your pregnancy can harm the heart and kidneys of your unborn baby, which can decrease the amount of the liquid (amniotic fluid) that surrounds and protect your unborn baby during pregnancy. Complications can occur with low levels of amniotic fluid. Receiving PERICOB 40 at the end of pregnancy can also expose the mother and the unborn baby to too much bleeding and can prevent the tightening of the muscles of the uterus, causing a delay in the delivery of the baby.

Breastfeeding

If you are breastfeeding, you must not receive PERICOB 40, as a small amount of PERICOB 40 will be transferred to your breast milk.

Fertility

NSAIDs, including PERICOB 40, 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 PERICOB 40 injection makes you feel dizzy or tired, do not drive or use machines until you feel better again.

3. How to receive PERICOB 40

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

You will not be expected to give yourself PERICOB 40. It will be given to you by a person who is qualified to do so. 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 PERICOB 40 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 80 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

If PERICOB 40 is used with strong pain killers (called opioid analgesics) such as morphine the dose of PERICOB 40 will be the same as explained above.

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

If you receive more PERICOB 40 than you should

Since a health care provider will administer PERICOB 40, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of PERICOB 40

Since a health care provider will administer PERICOB 40, it is unlikely that the dose will be missed.

4. Possible side effects

PERICOB 40 can have side effects.

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

If any of the following happens, stop receiving PERICOB 40 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- if you develop a rash or ulceration in any part of your body (e.g. skin, mouth, eyes, face, lips or tongue),

- if you 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.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- if you have blistering or peeling of the skin,
- 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- nausea (feeling sick),
- change in your blood pressure (up or down),
- you may get back pain,
- ankles, legs and feet may swell (fluid retention),
- you may feel numb - your skin may lose sensitivity to pain and touch,
- you may get vomiting, stomachache, indigestion, constipation, bloating and

wind,

- tests may show abnormal kidney function,
- you may feel agitated or find it hard to sleep,
- dizziness,
- there is a risk of anaemia - changes in red blood cells after an operation that may cause fatigue and breathlessness,
- you may get a sore throat or difficulty breathing (shortness of breath),
- your skin may be itchy,
- you may pass less urine than usual,
- dry socket (inflammation and pain after a tooth extraction),
- increased sweating,
- low levels of potassium in blood test results.

Less frequent

- heart attack,
- there is a 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,
- you may bruise easily due to a low blood platelet count,
- surgical wounds may become infected, abnormal discharge from surgical wounds,

- skin discolouration or bruising,
- complications with skin healing after operations,
- high sugar levels in blood tests,
- injection site pain or injection site reaction,
- 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,
- earache,
- unusual abdominal sounds,
- acute kidney failure,
- hepatitis (inflamed liver),
- inflammation of the gullet (oesophagus),
- inflammation of the pancreas (can lead to stomach pain).

Frequency unknown

- collapse due to severe low blood pressure,
- heart failure,
- kidney failure,
- racing or irregularity of the heartbeat,
- breathlessness.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PERICOB 40.

5. How to store PERICOB 40

Store all medicines out of reach of children.

- Store the un-reconstituted vial at or below 30 °C.
- Do not use after the expiry date stated on the label.
- Chemical and physical in-use stability of the reconstituted solution, which should not be refrigerated or frozen, have been demonstrated for up to 24 hours at 25 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PERICOB 40 contains

- The active substance is parecoxib. Each 5 ml vial contains 40 mg parecoxib (as 42,36 mg parecoxib sodium). After reconstitution, the concentration of parecoxib is 20 mg/ml. Each 2 ml of reconstituted powder contains 40 mg of parecoxib.
- The other ingredients are:

  PERICOB 40 vial: disodium phosphate anhydrous, o-phosphoric acid, sodium hydroxide and water for injection.

What PERICOB 40 looks like and contents of the pack

PERICOB 40 vial: White to off-white, lyophilised powder in a single use vial.

Parecoxib powder for injection 40 mg is packed in 5 ml Type I glass vial with bromobutyl rubber stopper and an aluminium flip off seal.

Pack size: 10 x 5 ml vials

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

Website address: https://pi-pil-repository.sahpra.org.za

Ascendis Pharma (Pty) Ltd:

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