PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

RAYZON® 40 mg IV/IM Powder for solution for injection

Parecoxib sodium

Sugar free

Read all of this leaflet carefully before you are given RAYZON

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

What is in this leaflet

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

1. What RAYZON is and what it is used for

RAYZON is an injection used to treat mild to moderate post-operative pain including pain after hip surgery. RAYZON contains the active ingredient parecoxib and belongs to a group of medicines called specific cyclooxygenase-2 (COX-2) inhibitors. 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 RAYZON

You should not be given RAYZON:

- if you are hypersensitive (allergic) to parecoxib or to any of the ingredients in RAYZON (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
- 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 RAYZON. Tell your doctor or health care provider before given the injection:

- if you have or have had heart disease or high blood pressure
- if you have diabetes
- if you have high cholesterol
- if you smoke
- if you have had an ulcer, bleeding, or hole or tear in your stomach and/or intestine
- if you experience a serious skin reaction, you need to tell your doctor or nurse immediately
- if you have liver or kidney disease
- if you could be dehydrated, for example by sickness or diarrhoea or the use of diuretics
- if you have fluid retention (oedema i.e. swelling of feet and ankles)
- if you are using any other types of painkillers or anti-inflammatory medicines (NSAIDs)

- if you have an infection, as it may hide fever and delay the detection of the cause of the fever
- if you receive RAYZON while you are pregnant, it can harm your unborn baby.

Other medicines and RAYZON

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

Before your first RAYZON injection is administered to you, make sure your doctor knows if you are taking:

- aspirin
- ACE inhibitors (used for high blood pressure and heart failure)
- ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants)
- diuretics (used to treat fluid retention)
- fluconazole or ketoconazole (used to treat fungal infections)
- lithium (used to treat depression)
- warfarin (used to prevent blood from clotting)
- digoxin (used for heart failure)
- other medicines to treat cough, diabetes, pain and rheumatoid arthritis

Pregnancy and breastfeeding

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 this medicine.

- if you are pregnant, or trying to become pregnant, you must not receive RAYZON. The unborn or newborn baby may be harmed, and the onset of labour may be delayed and its duration increased if RAYZON is used during the last 3 months of pregnancy
- if you are breastfeeding, you must not receive RAYZON, as a small amount of RAYZON can be transferred to the breastmilk. It is best to stop breastfeeding altogether before you are given RAYZON

Driving and using machines

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

It is not always possible to predict to what extent RAYZON may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RAYZON affects them.

3. How to receive RAYZON

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

You will not be expected to give yourself RAYZON. 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 over 65 years of age and weigh less than 50 kg.

Opioid analgesics can be used together with RAYZON as described above for the relief of pain.

RAYZON should not be used for longer than 48 hours in patients following hip replacement surgery.

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

If you receive more RAYZON than you should

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

If you miss a dose of RAYZON

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

4. Possible side effects

RAYZON can have side effects.

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

RAYZON may cause the following reactions. Tell your doctor immediately:

- if you have cardiac symptoms such as shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm
- if you experience dizziness and headache
- if you have an allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing
- if you have blistering or peeling of the skin
- if you have any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements, or vomiting blood

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
- problems sleeping
- numbness or loss of sensitivity to touch or sensation
- dizziness
- blood pressure may become lower
- difficulty breathing
- stomach ache, indigestion or constipation
- nausea and vomiting
- 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)
- a severe, potentially life-threatening allergic reaction
- high blood sugar
- anorexia (loss of appetite)
- feeling agitated
- risk of stroke or blockage to blood vessels to the heart
- earache
- slower or irregular heartbeat and palpitations
- heart failure or heart attack
- blood clots in the lungs
- blood pressure may become higher, or if you already have high blood pressure, it may become worse
- low blood pressure on standing
- dry mouth
- flatulence (bloating and wind)
- 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
- bruising of the skin
- rash, or raised itchy rash (hives)
- joint pain
- back pain
- acute kidney failure

- tests may show abnormal liver or kidney function
- injection site pain or injection site reactions
- lack of energy

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 RAYZON.

5. How to store RAYZON

- Store all medicines out of reach of children.
- RAYZON should be stored at or below 30°C in the outer container and protected from light.
- Your doctor or nurse will use RAYZON as soon as possible after it is mixed with the solvent.
- RAYZON should not be used after the expiry date stated on the label.

6. Contents of the pack and other information

What RAYZON 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 RAYZON looks like and contents of the pack

RAYZON powder is a white to off-white dry powder in a stoppered clear glass vial.

When mixed, the solution is clear and colourless.

RAYZON is supplied as a sterile, single unit-of-use vial, sealed with a purple flip-off cap These are packed in sets of either 1, 3, 5 or 10 vials together in an outer carton. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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