

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

RAYZON® 40 mg IV/IM Powder and Solvent for Solution for Injection

Read this leaflet carefully before you are given a RAYZON INJECTION.

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

1. WHAT RAYZON CONTAINS:

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.

The liquid solvent to dissolve the powder contains sodium chloride and water for injections. Small amounts of hydrochloric acid or sodium hydroxide may have been added for pH adjustment.

2. WHAT RAYZON IS USED FOR:

RAYZON is used to treat mild to moderate post-operative pain 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.

Your body makes substances called prostaglandins. Some prostaglandins cause pain and swelling, whilst others help protect the stomach lining. RAYZON works by reducing the amount of prostaglandins which produce pain and swelling without reducing the protective prostaglandins in the stomach.

Following hip replacement surgery, RAYZON can also be used for up to 48 hours, together with strong pain killers (opioid analgesics) such as morphine. It can reduce the amount of opioid analgesics used to achieve pain control and the side effects related with these medicines.

3. BEFORE YOU ARE GIVEN A RAYZON INJECTION:

You should not be given a RAYZON INJECTION:

- if you have had an allergic reaction to any of the ingredients in RAYZON
- if you have had an allergic reaction to a group of medicines called “sulphonamides” (e.g. some antibiotics 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 a stomach or duodenal ulcer, or bleeding in the stomach
- if you have severe liver or kidney disease
- if you have oedema (fluid retention)
- if you have severe heart failure, high blood pressure or if you have had a stroke
- if you are about to have coronary artery bypass graft surgery
- if you are pregnant or it is possible that you could become pregnant
- if you are breastfeeding

Take special care with RAYZON:

Some people will need special care from their doctors when they are taking RAYZON. Make sure that your doctor or nurse knows before you start taking RAYZON:

- 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 perforation of the gastrointestinal tract
- 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 an infection, as it may hide fever

Taking other medicines with RAYZON:

If you are taking other medicines on a regular basis including complementary and traditional medicines, concomitant use of RAYZON may cause undesirable interactions. Please inform your doctor or nurse if you are taking or have recently taken any other medicines, even those not prescribed.

Before your first RAYZON injection, 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)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat

4. HOW TO RECEIVE RAYZON INJECTION:

RAYZON will be given to you by a doctor or nurse only if alternative oral medication is not available. They will dissolve the powder before giving you the injection, and will inject the solution into a vein or a muscle. You will only be given RAYZON for short periods, and only for pain relief.

If there are particles in the injection solution or if either the powder or solution is discoloured, RAYZON will not be used.

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. In a clinical study, the daily requirement for opioid analgesics was much reduced when given together with RAYZON. More effect is achieved when RAYZON is given before the opioid analgesics. RAYZON should not be used for longer than 48 hours in patients following hip replacement surgery.

5. 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 while taking RAYZON, please consult your doctor or nurse for advice.

RAYZON INJECTION 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 blood-stained bowel movements, or vomiting blood

Frequent side effects are listed below:

- blood pressure may become higher or lower
- dizziness
- back pain
- ankles, legs and feet may swell (fluid retention)
- numbness
- stomach ache, indigestion, bloating and wind or constipation
- nausea and vomiting
- tests may show abnormal kidney function
- feeling agitated or problems sleeping
- anaemia
- sore throat or difficulty breathing
- itchy skin or rash
- urinating less than usual
- increased sweating

Less frequent side effects are listed below:

- slower or irregular heartbeat and palpitations

- blood tests may show abnormal liver function
- bruising (or low blood platelet count)
- low blood sugar
- surgical wounds may become infected
- earache or joint pain
- risk of stroke

6. STORAGE AND DISPOSING OF RAYZON:

Keep all medicines out of reach of children.

There are no special storage instructions. Your doctor or nurse will use RAYZON as soon as possible after it is mixed with the solvent.

The product should not be used after the expiry date stated on the label.

7. PRESENTATION OF RAYZON INJECTION:

RAYZON is supplied as a sterile, single unit-of-use vial, sealed with a purple flip-off cap, packaged together with a 2 ml ampoule containing the solvent. These are packed together in an outer carton.

8. IDENTIFICATION OF RAYZON INJECTION:

RAYZON powder is a white to off-white dry powder in a stoppered clear glass vial. RAYZON solvent is a clear, colourless solution.

When mixed, the solution is clear and colourless.

9. REGISTRATION NUMBERS:

RAYZON 40 mg IV/IM: 36/2.9/0119

RAYZON 2 ml SOLVENT: 36/34/0122

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton, 2196

South Africa

11. DATE OF PUBLICATION:

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