



Prescribe the
First and Only
IV/IM COX-2
Specific Inhibitor with
confidence

- ✓ **Confidence in effective pain relief**
 - Inhibits COX-2 centrally and peripherally
 - Anti-inflammatory and analgesic activity

- ✓ **Confidence in overall safety***
 - Improved GI and platelet safety^{1,2}
 - CV risk in general surgery similar to placebo³

- ✓ **Confidence in easy dosing**
 - 40 mg IV/IM followed by further 40 mg (maximum 80 mg daily)

* Refer to boxed warning in package insert.



Rayzon[™]
(parecoxib sodium)
IV/IM

Works fast...and lasts

RAYZON 40 MG IV/IM. COMPOSITION: Each vial contains 40 mg parecoxib for reconstitution. RAYZON 2 ML SOLVENT: Each ampoule contains 2 ml sodium chloride intravenous infusion (0.9% w/v) BP. **PHARMACOLOGICAL CLASSIFICATION:** A 2.9 Other Analgesics. **INDICATIONS:** For the management of post operative pain. **CONTRA-INDICATIONS:** Hypersensitivity to the active substance or to any other ingredient of the product. History of hypersensitivity to sulphonamides. Bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria or allergic-type reactions after taking acetylsalicylic acid or NSAIDs or other cyclooxygenase-2 (COX-2) specific inhibitors. Severe impairment of hepatic or renal function. Peri-operative analgesia in the setting of coronary artery bypass surgery (CABG). Established ischaemic heart disease and/or cerebrovascular disease (stroke) and peripheral arterial disease. **Pregnancy and lactation.** Children younger than 18 years. **WARNINGS:**

Rayzon may predispose to cardiovascular events, cerebrovascular events, gastro-intestinal events or cutaneous reactions which may be fatal. **DOSAGE AND DIRECTIONS FOR USE:** A single or initial 40 mg dose administered intravenously (IV) or intramuscularly (IM), followed every 6 to 12 hours by 40 mg as required, not to exceed 80 mg/day. The IV bolus injection may be given rapidly and directly into a vein or into an existing IV line. The IM injection should be given slowly and deeply into the muscle. **Elderly:** No dosage adjustment is generally necessary. Elderly female patients weighing > than 50 kg, initiate treatment with half the usual recommended dose of RAYZON Injection and reduce the maximum daily dose to 40 mg. **Hepatic Impairment:** No dosage adjustment is generally necessary in patients with mild hepatic impairment (Child-Pugh scale 5-6). Introduce RAYZON Injection with caution and at half the usual recommended dose in patients with moderate hepatic impairment (Child-Pugh scale 7-9) and reduce the maximum daily dose to 40 mg. Contra-indicated in severe hepatic impairment (Child-Pugh scale > 9). **Renal Impairment:** No dosage adjustment is necessary in patients with mild to moderate (creatinine clearance of 30-80 ml/min.) or severe (creatinine clearance < 30 ml/min.) renal impairment. However, caution should be observed in patients with severe renal impairment or patients who may be predisposed to fluid retention. **Children:** RAYZON Injection has not been studied in patients under 18 years old. Therefore, its use is not recommended in these patients. **SIDE-EFFECTS: (Common; >1/100 and < 1/10)** Post-operative anaemia, hypotension, respiratory insufficiency, alveolar osteitis, dyspepsia, flatulence, pruritis, back pain, oliguria, peripheral oedema, creatinine increase. **(Uncommon; >1/1000 and <1/100)** Abnormal sternal serous wound drainage, wound infection, thrombocytopenia, cerebrovascular disorder, bradycardia, aggravated hypertension, ecchymosis, AST increased, ALT increased. BUN increased. **PRECAUTIONS:** RAYZON Injection should be used with caution in patients with severe renal impairment (creatinine clearance < 30 ml/min.) or moderate hepatic impairment (Child-Pugh scale 7-9). Contra-indicated in severe hepatic impairment (Child-Pugh scale > 9). Caution should be observed when administering RAYZON Injection in patients with compromised renal, cardiac or hepatic function or other conditions predisposing to fluid retention. Caution should be used when initiating treatment with RAYZON Injection in patients with considerable dehydration. It is advisable to rehydrate patients first and then start therapy with RAYZON Injection. Hypersensitivity reactions such as anaphylaxis and angioedema have been reported in post-marketing experience with valdecoxib and cannot be ruled out for RAYZON Injection. Some of these reactions have occurred in patients with a history of allergic-type reactions to sulphonamides. Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in post-marketing experience with valdecoxib and cannot be ruled out for RAYZON Injection. RAYZON Injection should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity. RAYZON Injection may mask fever. Caution should be exercised with respect to monitoring the incision for signs of infection in patients receiving RAYZON Injection. Upper gastrointestinal perforations, ulcers or bleeds (PUBs) have occurred in patients treated with RAYZON Injection, therefore caution should be taken in patients with a history of PUBs. Safety and efficacy of RAYZON Injection have not been established for periods of use exceeding 96 hours. **REGISTRATION NUMBERS:** RAYZON 40 MG IV/IM: 36/2.9/0120 RAYZON 2 ML SOLVENT: 36/34/0122 **NAME AND ADDRESS OF LICENCE HOLDER:** Pfizer Laboratories (Pty) Ltd. Reg. No. 1954/00781/07. 102 Rivonia Road, Sandton, 2196. P.O. Box 783720, Sandton, 2146. Tel: 0860 PFIZER (734 937), Fax (011) 895 1404. **DATE OF PUBLICATION OF THIS PACKAGE INSERT:** August 2005. For more information refer to the detailed RAYZON package insert. 28/RAY/11/05/JA

References:

1. Noveck RJ, Laurent A, Kuss M, Talwalker S, Hubbard RC. Parecoxib sodium does not impair platelet function in healthy elderly and non-elderly individuals: two randomized, controlled trials. *Clin Drug Invest.* 2001;21:465-476. 2. Stolz RR, Harris SI, Kuss ME et al. Upper GI Mucosal Effects of Parecoxib Sodium in Healthy Elderly subjects. *Am Jnl of Gastroenterology.* 2002;97(1):65-71. 3. Whelton A; Singla NK, Minkowitz HS, et al. The Parenteral COX-2 Specific Inhibitor, Parecoxib, followed by Oral Valdecoxib, is safe and well tolerated in the Treatment of Acute Pain in Orthopaedic of General Surgery setting. SCA 2005. Study 069.