Abridged Prescribing Information:

Active Ingredient NUREETO-MR 4 tablet contains Etoricoxib 60 mg plus Thiocolchicoside 4 mg

NUREETO-MR 8 tablet contains Etoricoxib 60 mg plus Thiocolchicoside 8 mg

Indication: NUREETO-MR tablets are indicated for the short-term treatment of traumatic, inflammatory or neurogenic muscle spasms and also, painful musculoskeletal conditions where muscle spasm contributes to pain, viz., low back pain, sciatica, radiculopathy-associated pain, and spondylosis, in adults**. Dosage & Administration**: NUREETO-MR tablets should always be administered orally with food and not exceeding a period of 7 days. The recommended initial dose in adults is one NUREETO-MR 4 tablet to be taken orally twice daily after food (total dose - etoricoxib 120 mg/day, thiocolchicoside 8 mg/day). After a day or two, on the basis of individual patient response, if a stronger muscle relaxant effect is required, switch to one NUREETO-MR 8 tablet given twice daily (total dose - etoricoxib 120 mg/day, thiocolchicoside 16 mg/day) replacing NUREETO-MR 4 tablets. The maximum daily dose of two NUREETO-MR 8 tablets (total dose - etoricoxib 120 mg/day, thiocolchicoside 16 mg/day) should not be exceeded. After 7 days, replace NUREETO-MR tablets with etoricoxib tablets or other anti-inflammatory agents as necessary. **Contraindication:** Hypersensitivity to any component of this product; a history of asthma, urticaria, or other allergic reactions after taking aspirin or other NSAIDs, congestive heart failure (NYHA II-IV), hypertension whose blood pressure is persistently elevated above 140/90 mm Hg and has not been adequately controlled, established ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease (including patients who have recently undergone coronary artery bypass graft surgery or angioplasty). **Warnings & Precautions: Cardiovascular effects:** COX-2 selective inhibitors are not a substitute for acetylsalicylic acid for cardiovascular prophylaxis because of their lack of effect on platelets. Because etoricoxib, a member of this class, does not inhibit platelet aggregation, antiplatelet therapies should not be discontinued and if indicated should be considered in patients at risk of or with a history of cardiovascular or other thrombotic events. Caution should be exercised in patients with a medical history of ischaemic heart disease. **Renal effects:** Renal prostaglandins may play a compensatory role in the maintenance of renal perfusion. Therefore, under conditions of compromised renal perfusion, administration of etoricoxib may cause a reduction in prostaglandin formation and secondarily, in renal blood flow and thereby impair renal function. **Fluid retention, edema and hypertension:** As with other drugs known to inhibit prostaglandin synthesis, fluid retention and oedema have been observed in patients taking etoricoxib. Caution should be exercised in patients with a history of cardiac failure, left ventricular dysfunction or hypertension and in patients with pre-existing oedema due to any other reason. **Pregnancy:** Pregnancy category C. - As with other drugs known to inhibit prostaglandin synthesis, use of etoricoxib should be avoided in late pregnancy because it may cause premature closure of the ductus arteriosus. There are no adequate and well-controlled studies in pregnant women. Etoricoxib should be used during the first two trimesters of pregnancy only if the potential benefit justifies the potential risk to the foetus. Studies conducted in animals have shown a reproductive toxicity. In humans, there is no pertinent data for the use of thiocolchicoside in pregnant woman. Thus, the potential hazards for the embryo and fetus are unknown. In consequence, thiocolchicoside should not be used during pregnancy. **Special Population**: **Hepatic Insufficiency:** In patients with mild hepatic insufficiency (Child-Pugh score 5-6), a dose of one NUREETO-MR 4 tablet once daily should not be exceeded. In patients with moderate hepatic insufficiency (Child-Pugh score 7-9), the dose should be reduced; a dose of one NUREETO-MR 4 tablet once every alternate day should not be exceeded. Not recommended in patients with severe hepatic insufficiency (Child-Pugh score >9). **Renal Insufficiency:** In patients with advanced renal disease (creatinine clearance <30 mL/min), treatment with NUREETO-MR is not recommended. No dosage adjustment is necessary for patients with lesser degrees of renal insufficiency. **Adverse Reactions: Etoricoxib**: In many clinical reports, the most common adverse events found in arthritic patients treated with etoricoxib were: asthenia/fatigue, dizziness, lower extremity edema, hypertension, dyspepsia, heartburn, nausea, headache, ALT increased, AST increased. **Thiocolchicoside:** Rare cases of gastrointestinal disorders such as diarrhea, gastralgia, nausea, vomiting, cutaneous allergic reactions, including angioedema and drowsiness have been reported. **Overdose: Etoricoxib**: In clinical studies, administration of etoricoxib at single doses up to 500 mg and multiple doses up to 150 mg/day for 21 days did not result in significant toxicity. There have been reports of acute overdosage with etoricoxib, although adverse events were not reported in the majority of cases. The most frequently observed adverse events were consistent with the safety profile for etoricoxib (e.g. gastrointestinal events, renovascular events). In the event of overdose, it is reasonable to employ the usual supportive measures, e.g., employ clinical monitoring, and institute supportive therapy, if required. Etoricoxib is not dialysable by haemodialysis; it is not known whether etoricoxib is dialysable by peritoneal dialysis. **Thiocolchicoside:** No overdose symptoms have been reported in patients treated with thiocolchicoside. In case of overdose, medical supervision and symptomatic measures are recommended.

(For details, please refer full prescribing information)

Version date: 03/03/2023. If you require any further information, please reply us on

productqueries@intaspharma.com