[말레이시아]
로시덴주 설명서
Size : 120 × 245 (mm)

수정사항
1. Zypas 주소 추가
2. 공간확보 위한 전체 Layout 수정

Non-steroidal Anti-inflammatory, Analgesic Agent

ROSIDEN 20mg/mL Injection

[DESCRIPTION]
ROSIDEN Injection contains Piroxicam, which is a nonsteroidal anti-inflammatory agent (NSAIA). Piroxicam occurs as a white, crystalline solid and is sparingly soluble in water and slightly soluble in alcohol and in alkaline aqueous solution.

[COMPOSITION]
Each ampoule (1mL) of ROSIDEN Injection contains 20mg of Piroxicam and benzyl alcohol 0.9%.

[INDICATIONS]
- ROSIDEN is indicated for the symptomatic relief of pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.
- However, it should not be the first choice of Non-Steroidal Anti-Inflammatory Drug (NSAID) treatment in these conditions.

[DOSAGE AND ADMINISTRATION]
ROSIDEN Injectable solution has to be injected I.M. (deep intragluteally).
- The maximum recommended daily dose is 20 mg.
- After assessing the risk/benefit ratio in each individual patient, undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms. Treatment should be reviewed after 14 days.
- Combination therapy with gastro-protective agents should be carefully considered for patients at high risk of gastrointestinal complications.

[CONTRAINDICATIONS]
ROSIDEN should not be used in:
- In children under 2 years and in patients hypersensitive to benzyl alcohol.
- Patients with active or history of gastrointestinal ulceration, bleeding, perforation or any gastrointestinal disorders that predispose to bleeding such as Crohn's disease, ulcerative colitis, gastrointestinal cancers or diverticulitis.
- Patients on concomitant NSAIDs or anticoagulants.
- Patients with a history of previous serious allergic drug reaction of any type such as Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme.
- Patients who are hypersensitive to the active substance, previous skin reaction to piroxicam, other NSAIDs or other medications.

[SPECIAL PRECAUTIONS AND WARNINGS]
Cardiovascular Thrombotic Events
- Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events, principally myocardial infarction, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk of an adverse cardiovascular event in patients taking NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration. There is no consistent evidence that the concurrent use of aspirin mitigates the possible increased risk of serious cardiovascular thrombotic events associated with NSAID use.

Hypertension
- NSAIDs may lead to the onset of new hypertension or worsening the pre-existing hypertension and patients taking antihypertensive with NSAIDs may have an impaired antihypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.

Heart Failure
- Fluid retention and oedema have been observed in some patients taking NSAIDs; therefore caution is advised in patients with fluid retention or heart failure.

Gastrointestinal Events
- All NSAIDs can cause gastrointestinal discomfort and rarely serious, potentially fatal gastrointestinal effects such as ulcers, bleeding and perforation, which may increase with dose or duration of use, but can, occur at any time without warning. Caution is advised in patients with risk factors for gastrointestinal events e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. When gastrointestinal bleeding or ulcerations occur in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patient about signs and symptoms of serious gastrointestinal toxicity. The concurrent use of aspirin and NSAIDs also increase the risk of serious gastrointestinal adverse events.
- NSAID exposures of both long and short duration have an increased risk of serious GI event. Evidence from observational studies suggests that piroxicam may be associated with a high risk of serious gastrointestinal toxicity, relative to other NSAIDs.
- The risk for developing serious gastrointestinal complications increases with age. Patients taking concomitant oral corticosteroids, selective serotonin reuptake inhibitors (SSRIs) or anti-platelet agents are also at increased risk of serious gastrointestinal complications.

Severe Skin Reactions
- NSAIDs may very rarely cause serious cutaneous adverse events, such as exfoliative dermatitis, toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), which can be fatal and occur without warning. These serious adverse events are idiosyncratic and are independent of dose or duration of use. Patients should be advised of the signs and symptoms of serious skin reactions and to consult their doctor at the first appearance of a skin rash or any other sign of hypersensitivity.
- Evidence from observational studies suggests that piroxicam may be associated with a higher risk of serious skin reactions than other non-oxicam NSAIDs

[OTHER PRECAUTIONS]
- If ROSIDEN must be given to patients with a history of upper gastrointestinal tract disease, the patient should be under observation on dosing.
- Although other non-steroidal anti-inflammatory drugs do not have the same direct effects on platelets that aspirin does, all drugs inhibiting prostaglandin biosynthesis interfere with platelet function to some degree; therefore, patients who may be adversely affected by such an action should be carefully observed when ROSIDEN is administered.
- As with other non-steroidal anti-inflammatory drugs, transient elevations of BUN value may occur in some cases. But, because of extensive renal excretion of Piroxicam and its biotransformation products, lower- doses of Piroxicam should be anticipated in patients with impaired renal function and they should be carefully monitored.
- Peripheral edema has been observed in the patients treated with ROSIDEN.
- ROSIDEN is highly protein bound, and therefore, might be expected to displace other protein bound drugs. Although this has not occurred in in-vitro studies with coumarin-type anticoagulants, interactions with coumarin-type anticoagulants have been reported with ROSIDEN since marketing; therefore, physicians should closely monitor patients for a change in dosage requirements when administering ROSIDEN to patients on coumarin-type anticoagulants and other highly protein-bound drugs.
- Plasma levels of Piroxicam are depressed to approximately 80% of their normal values when ROSIDEN is administered in conjunction with aspirin, but concomitant administration of antacids or digoxin has no effect on Piroxicam plasma levels.
- Non-steroidal anti-inflammatory agents, including ROSIDEN, have been reported to increase steady state plasma lithium levels. It is recommended that plasma lithium levels be monitored when initiating, adjusting and discontinuing ROSIDEN.
- Treatment should always be initiated by a physician experienced in the treatment of Rheumatic arthritis

【OTHER WARNINGS】

- Pregnancy and nursing mothers : Even though teratology is not observed in animal study, safety has not been established for use in pregnancy and nursing mothers.
- Like other nonsteroidal antiphlogistics, which inhibit the synthesis and release of prostaglandins, Piroxicam increased the incidence of dystocia and delayed parturition in pregnant animals when Piroxicam administration was continued in the later pregnancy.
- In addition, these drugs are known to induce occlusion of ductus arterious in fetus. In preliminary study, Piroxicam is measured 1% of plasma level in mother's milk. ROSIDEN is prohibited for use in nursing mothers since safety has not been established in human.
- Use in children : Dosage recommendations and indications for use in children have not been established.

RISK OF G.I. ULCERATION, BLEEDING, AND PERFORATION WITH NSAID
Serious G.I. toxicity such as bleeding, ulceration, and perforation can occur at any time, with or withoutwarning symptoms, in patients treated with NSAID therapy. Although minor G.I. problems (e.g. dyspepsia) are common, usually developing early in therapy, doctors or pharmacists should remain alertfor ulceration and bleeding in patients treated with NSAIDs even in the absence of previous G.I. tractsymptoms. In patients observed in clinical trials of several months to 2 years duration, symptomatic upperG.I. ulcers, gross bleeding, or perforation occurred in approximately 1% of patients treated for 3 to 6months, and in about 2% to 4% of patients treated for 1 year. Higher percentages have been reported by other independent studies. Studies up to date have not identified any subset of patients not at risk ofdeveloping peptic ulceration and bleeding. Patients with prior history of serious G.I events and other riskfactors associated with peptic ulcer disease (e.g. alcoholism, smoking, corticosteroid therapy) are atincreased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than otherindividuals and account for most spontaneous reports for fatal G.I. events. Measures such as the use of physical therapy and mild analgesics like paracetamol (When inflammation isnot a major factor) should be instituted prior to initiation of therapy with NSAID, NSAIDs should be used only after proper appraisal of potential risks to patients. It should be used with the lowest effective dose for only as long as needed. This drug should not be co-administered with other NSAIDs. Doctors and pharmacistsshould inform patients of the signs and/or symptoms of serious G.I. toxicity and what steps to take if they occur. In considering the use of relatively large doses (within the recommended dosage range), sufficient benefit should offset the potential increased risk of G.I. toxicity.

【ADVERSE REACTIONS】

- Tolerance of this drug is generally good.
- General adverse reactions of this drug are gastric symptoms as follows; Stomatitis, retching, anorexia, epigaustralgia constipation, abdominal malaise, abdominal distention, diarrhea, abdominal pain, and bradypepsia. But most of those symptoms are not harm during the process of the treatment. According to the objective valuation related to the affection and the enterohemorrhage of gastric mucosa, the stimulation to gastro-intestinal tract of this drug was known much less than that of aspirin when 20mg of dosage was administered once or several times divisionally a day.
- A danger of side effects related to gastro-intestinal tract would be increased when 30mg of constant administration or 30mg over. Excepting for gastric symptoms, ankle edema was reported in a very small number of cases.
- Side effects such as dizziness, headache, giddiness, and convulsion related to central nervous system were also reported.
- A change of eyes was not found in slit-lamp test.
- Fatigue and tinnitus may be occurred, and itching and eruption were found as hypersensitive dermo-reaction.
- The reactions of extent-allergy related to treatment were found in a small number of cases.
- As with other nonsteroidal antiphlogistics, erythema exsudatirum multiforme may be manifested in a very small number of cases.
- A change was observed in liver-function test.
- Like most other nonsteroidal antiphlogistics, ascension of serum transaminase may be occurred during treatment with this drug in some patients.

【DRUG INTERACTIONS】

- NSAIDs : Concomitant use with other NSAIDs must be avoided since the potential for adverse reactions is enhanced, with inadequate data to show that such combinations produce greater benefit compared to piroxicam monotherapy.
- Corticosteroids: Concomitant use leads to increased risk of gastrointestinal ulceration or bleeding.
- Anticoagulants: Concomitant use should be avoided due to enhanced effects of anticoagulants.
- Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): Concomitant use leads to increased risk of gastrointestinal bleeding.

【INCOMPATIBILITIES】 None

【SYMPTOMS AND TREATMENT OF OVERDOSAGE AND ANTIDOTES】
In the event treatment for overdosage is required, the long plasma half-life of piroxicam should be considered. The absence of experience with acute overdosage precludes chacterization of sequelae and recommendation of specific antidotal efficacy at this time. It is reasonable to assume, however that the standard measures of gastric evacuation and general supportive therapy would apply. In addition to supportive measures, the use of activated charcoal may effectively reduce the absorption and re-absorption of piroxicam. Experiments in dogs have demonstrated the use of multiple dose treatments with activated charcoal could reduce the half-life of piroxicam elimination from 27 hours (without charcoal) to 11 hours and reduce the systemic bioavailability of piroxicam by as much as 31% when activated charcoal is given as late as 6 hours after administration of piroxicam.

【STORAGE】
Store in hermetic and light resistant container below 30℃.

【EXPIRY】
3 years from the manufacturing date

【HOW SUPPLIED】
1ml/Ampoule × 10

As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

Product Registration Holder :
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