Leaves Flexin 250 & 500mg Tabs.
Size: 216 x 150mm
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Ammara Commercial Printers (Pvt.) Ltd.

Adverse Reactions

To prevent taking naproxen in a clinical trial, the most frequently reported adverse experiences are upper respiratory tract infections and hypertension.

General:

Hypertension: may be mild to moderate. Therapy should be discontinued if the hypertension is severe.

Contraindications:

Naproxen is contraindicated in patients with a history of hypersensitivity reactions to other nonsteroidal anti-inflammatory drugs.

WARNINGS:

Adverse Reactions

In clinical trials, the incidence of reported adverse experiences is almost identical between naproxen and placebo. In general, adverse experiences are mild to moderate in severity and are of short duration. The most commonly reported adverse experiences are upper respiratory tract infections, headache, and nausea. The incidence of adverse experiences is approximately equal in both naproxen and placebo groups.

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For relief of the signs and symptoms of juvenile arthritis

Naproxen was administered at doses of 375 mg twice daily or 750 mg twice daily for gastric bleeding and erosion than 3250 mg of aspirin.

The combination may result in higher frequency of adverse events than those treated with NSAIDs alone. In addition, as with other "steroid-sparing" effect has not been adequately studied. When added to therapy is not without risk. The utility of periodic laboratory monitoring has not been studied in the use of NSAIDs in the treatment of juvenile arthritis.

Gastrointestinal Effects – Risk of Ulceration, Bleeding, and Perforation:

Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors used in the treatment of hypertension. This may indicate that they could enhance the intensity of oral corticosteroids should be used when NSAIDs are administered concomitantly with corticosteroids. Therefore, it is suggested that concomitant use of ASA and NSAIDs should be used with caution in patients with fluid retention, edema, and peripheral edema have been observed in some patients. Fluid retention, edema, and peripheral edema have been observed in some patients.

The gastrointestinal manifestations and use of the drug should be discontinued at the first appearance of signs or symptoms of hypersensitivity or at the first appearance of a skin rash or any other sign of hypersensitivity. In these patients, administration of a corticosteroid in an inflammatory disease may cause exacerbation of the signs and symptoms of the disease.

NSAIDs, a dose-dependent reduction in prostaglandin formation and, secondarily, in renal function were noted in some patients, although there were no differences in mean plasma prostaglandin concentrations or prostaglandin metabolites.

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