PONTALON® CAPSULE

A non-narcotic, well-tolerated analgesic with anti-inflammatory properties, Pontalon provides greater relief of pain than conventional analgesics. The potent anti-inflammatory property (five times greater than those of Acetyl-salicylic Acid) helps to broaden and extend the usefulness of Pontalon. Among the desired qualities of an analgesic agent are rapid onset and prolonged duration of action. With Pontalon, pain relief occurs within an hour after administration and is maintained for up to six hours.

Description:
A #2 pale green cap and white body hard gelatine capsule containing white powder, with a mark "PLC" printed on the capsule.

Ingredient(s):
Each capsule contains:
Mefenamic Acid ……..…….…….....…… 250mg

Action(s):
Pontalon is a non-steroidal agent which demonstrated anti-inflammatory, analgesic and antipyretic activities. It inhibits the enzyme cyclo-oxygenase, resulting in decreased formation of precursors of prostaglandins and thromboxanes from Arachidonic Acid. It has also been shown to inhibit competitively the actions of prostaglandins. These actions may contribute significantly to its therapeutic effects.

Indication(s):
For the relief of mild to moderate pain including muscular, traumatic and dental pain, headache, postoperative and postpartum pain, and dysmenorrhea.

Dosage and Administration:
Adults: The recommended initial dose is 500mg followed by 250mg every 6 hours as required and usually not to exceed one week. For dysmenorrhea, the recommended dosage is 500mg as an initial dose followed by 250mg every 6 hours, starting at the onset of menstrual pain and should not exceed for more than 2 - 3 days. Safe use of this drug in pregnancy has not been established.

Contraindication(s):
1. Pontalon should not be used in patients who have previously exhibited hypersensitivity to it.

2. Pontalon is contraindicated in patients with active ulceration or chronic inflammation of either the upper or lower gastrointestinal tract.

3. Pontalon should be avoided in patients with pre-existing renal disease.

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Precaution(s) / Warning(s):
Side effects are negligible at recommended dosage. Gastric irritation is infrequent and may be minimized by taking medication during meals. Long-term continuous administration of Pontalon in daily doses of 2g or more is not recommended. Furthermore, these doses are greater than those required for analgesia. Diarrhea may occur on long-term continuous dosage of 2g or more daily and is an indication to discontinue medication. Maculopapular rash may occur and it disappears on withdrawal of medication.
1. If diarrhea occurs, the dosage should be reduced or temporarily suspended.

2. If rash occurs, administration of the drug should be stopped.

3. It should be used with caution in patients with impaired renal or liver function.

4. It has marked tendency to induce grand mal convulsions in overdosage and should be avoided in epileptic subjects.

5. Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation.

Drug Interaction:
Mefenamic Acid enhances the effect of Warfarin. Therefore, where given to a patient receiving Warfarin, the dosage of Warfarin should be reduced to prevent excessive prolongation of the prothrombin time.
Aspirin administered concurrently may lower Mefenamic Acid plasma level, possibly by competing for protein-binding sites. The urinary excretion is unaffected by Aspirin, indicating no charge in absorption.
Mefenamic Acid does not affect serum Salicylate levels. Greater fecal blood loss results from concomitant administration of both drugs than from either drug alone.

Side Effect(s) / Adverse Reaction(s):
The commonest adverse effects occurring with Mefenamic Acid are gastrointestinal disturbances such as: diarrhea, nausea, vomiting and abdominal pain; other gastrointestinal adverse reactions occur less frequent are: anorexia, pyrosis, flatulence and constipation. Peptic ulceration and gastrointestinal bleeding have also been reported. Hypersensitivity reactions including skin rashes and urticaria, and occasionally allergic glomerulonephritis may occur. Asthma may be precipitated. Other side effects including headache, drowsiness, dizziness, nervousness, insomnia, facial edema and

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blurred vision, renal failure, including papillary necrosis have been reported. In elderly patients renal failure has occurred after 2 - 6 weeks of treatment. Renal failure may not be completely reversible. Hematuria and dysuria have also been reported.

Symptoms and Treatment for Overdosage and Antidote(s):
Treatment of overdosage consists of emptying the stomach via induction of emesis or gastric lavage, administration of activated charcoal and antacids, and monitoring and supporting vital functions. Induction of diuresis may be useful in overdosage with it.

Shelf-Life:
3 years from the date of manufacture.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Packing:
Plastic bottle of 200's, 1000's and 1500's.
Blister packing of 10's x 10, 10's x 120 and 10's x 100.
Not all presentations may be available locally.

WARNINGS

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor GI problems (eg. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms. In patients observed in clinical trials of several months to 2 years duration, symptomatic upper GI ulcers, gross bleeding or perforation occurred in approximately 1% of patients treated for 3 to 6 months, and in about 2% to 4% of patients treated for 1 year. Higher percentages have been reported by other independent studies.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (eg. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly of debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Measures such as the use of physical therapy and mild analgesics like Paracetamol (when inflammation is not a major factor) should be instituted prior to initiation of therapy with NSAID. NSAIDs should only be used after proper appraisal of potential risks to patients. It should only be used with the lowest effective dose for only as long as needed. This drug should not be co-administered with other NSAIDs. Prescribers should inform patients about the signs and/or symptoms of serious GI 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 GI toxicity.

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PONTALON® KAPSUL

Diskripsi:
Kapsul #2 dengan cap berwarna hijau muda dan badan berwarna putih, mengandungi serbuk putih di dalamnya dengan tanda "PLC" dicetak pada kapsul.

Bahan Aktif:
Setiap kapsul mengandungi:
Mefenamic Acid ……..…….....…… 250mg

Indikasi:
Untuk melegakan kesakitan otot, kepala, postoperasi, postpartum dan dismenorea.

Dos:
Dewasa: Dos permulaan 500mg diikuti 250mg setiap 6 jam bila perlu dan tidak melebihi satu minggu. Bagi dismenorea, dimakan bila kesakitan haid dan tidak melebihi 2 - 3 hari.

Y. S. P.®

Manufacturer and Product Registration Holder:
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Kawasan Perindustrian Bandar Baru Bangi,
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Product Registrant and Importer:
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