# PONTALON® TABLET

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.

**Ingredient(s):**
Each Pontalon tablet 250mg contains:
Mefenamic Acid …..... 250mg
Each Pontalon tablet 500mg contains:
Mefenamic Acid …..... 500mg

**Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics):**
**Pharmacodynamics:**
1. Mefenamic acid is a non-steroidal anti-inflammatory agent. It inhibits the cyclo-oxygenase enzyme and thus exerts its anti-inflammatory activity by inhibition of prostaglandin synthesis.
2. Mefenamic acid has antipyretic and analgesic properties acting by both central and peripheral mechanisms.
3. Mefenamic acid exhibits marked antirheumatic, anti-inflammatory, analgesic and antipyretic properties.

**Pharmacokinetics:**
1. Mefenamic acid is well absorbed after oral administration with peak plasma concentration occurring at 2 - 4 hours. The plasma half-life is around 3 hours, and protein binding is 99%.
2. Between 50 and 70% of a dose of Mefenamic acid is excreted in the urine as conjugates of glucuronic acid; 10% is mostly conjugated Mefenamic acid. 20% of the drug is recovered in the faeces mainly as unconjugated metabolite.

**Indication(s):**
For the symptomatic relief of degenerative arthralgia and for the relief of mild to moderate pain, including muscular, traumatic and dental pain, headache, postoperative and post-partum pain and dysmenorrhea.

**Dosage and Administration:**
For mild to moderate pain: 500mg three times daily in adult and adolescents over 14 years. For dysmenorrhea, 500mg as initial dose starting at the onset of menstrual pain followed by 250mg 6 hourly. Elderly > 70 years: half of the usual adult dose. After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

**Route of Administration:** Oral.

**Contraindication(s):**
1. Inflammatory bowel disease.
2. Peptic and/or intestinal ulceration.
3. Renal impairment.
4. Known hypersensitivity to this product, aspirin or other NSAIDs.

**Precaution(s) / Warning(s):**
1. Caution should be exercised in patients with a history of blood dyscrasias or disorders of coagulation
2. Diarrhea may occur early on or after several months. Prolonged use of the drug has been associated with proctocolitis and enteritis, which may be complicated by steatorrhoea.
3. The anti-inflammatory, antipyretic, and analgesic effects of Pontalon may mask the normal signs of infections. The physician should be alert to any development of infection in patients receiving Pontalon.
4. Mefenamic acid should be used with caution in patients with impaired liver function. Dosage reduction may be necessary to prevent accumulation of the medication.
5. In patients suffering from dehydration and renal disease, particularly the elderly, concurrent therapy with other plasma protein-binding drugs may necessitate a modification in dosage. In the case of anticoagulants, the dose of the anticoagulant may need to be reduced.
6. Mefenamic acid has a marked tendency to induce tonic-clonic (grand mal) convulsions in overdosage; some sources have suggested that it should be avoided in epileptic subjects.
7. Use in Pregnancy and lactation:
   Although adequate and well-controlled studies in human have not been done, it has been demonstrated that Mefenamic acid metabolites readily cross the placenta. Although no fetal abnormalities were reported in the animal studies, it has been recommended that Mefenamic acid not be used during pregnancy (FDA Pregnancy Category C).
8. 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 ulceration occurs in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patients about signs and symptoms of serious gastrointestinal toxicity. The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse events.
9. 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 patient 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.
10. NSAIDs may lead to the onset of new hypertension or worsening the pre-existing hypertension and patients taking anti-hypertensive with NSAIDs may have an impaired anti-hypertensive 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.
11. Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.
12. 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

reaction and to consult their doctor at the first appearance of a skin rash or any other sign of hypersensitivity.

13. Skin Reactions: Serious skin reactions such as Generalised bullous fixed drug eruption (GBFDE) have been reported very rarely in association with the use of mefenamic acid. Mefenamic acid should be discontinued at the first appearance of the skin rash, mucosal lesions or any other sign of hypersensitivity.

**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.

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 adverse events and other risk factors associated with peptic ulcer disease (eg. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

**Drug Interaction(s):**
Mefenamic acid enhances the effect of Warfarin. Therefore, when 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 levels, possibly by competing for protein-binding sites. The urinary excretion is unaffected by Aspirin, indicating no change 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):**
Mefenamic acid is usually well tolerated. The most common adverse effects are gastro-intestinal disturbances such as diarrhea, nausea, vomiting and abdominal pain. Peptic ulceration and gastro-intestinal bleeding have also been reported. Other side effects are headache, drowsiness, dizziness, visual disturbances, skin rashes and urticaria. Occasionally allergic glomerulonephritis, brochospasm and asthma precipitation. Haematological effects rarely occurred, including hemolytic anemia, thrombocytopenia, and bone marrow aplasia. Borderline elevations of one or more liver function tests may occur in some patients. Skin and subcutaneous tissue disorders: Generalised bullous fixed drug eruption (GBFDE).

**Symptoms and Treatment for Overdosage and Antidote(s):**
Deliberate overdose has been increasing though no deaths have yet been reported. Large doses produce excitement, incoordination, depression and convulsions in mice. Grand mal convulsions appear to be the most regularly observed adverse effect in man. These are commonly preceded by focal or generalized muscle twitching. If ingestion is recent, forced emesis or gastric lavage should be performed or activated charcoal then given (0.5 g/kg) which may considerably reduce absorption. Careful observation during the first few hours is recommended as convulsions are most likely to occur during this period. Very high serum levels may be associated with repeated convulsions which have been successfully suppressed with intravenous diazepam.

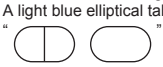
**Shelf-Life:**
3 years from the date of manufacture.

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

**Product Description and Packing(s):**
Pontalon tablet 250mg
A white color round tablet, one side with a mark “P”.


Plastic container of 90’s and 100’s.
Plastic container of 1200’s and 2500’s (for export only)

Pontalon tablet 500mg
A light blue elliptical tablet, one side impressed with a score.



Plastic container of 90’s
Plastic container of 100’s and 1000’s (for export only).

Y. S. P.

Manufacturer and Product Registration Holder:
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