YSP IBUPROFEN

Ibuprofen is a non-steroidal anti-inflammatory agent. It also possesses both analgesic and antipyretic properties. Its mode of action like that of other non-steroidal anti-inflammatory agents, may be related to prostaglandin synthetase inhibition.

Ingredient(s):
YSP Ibuprofen Capsule 200mg
Each capsule contains:
Ibuprofen 200mg
YSP Ibuprofen Film Coated Tablet 400mg
Each tablet contains:
Ibuprofen 400mg

Pharmacodynamics:
Ibuprofen inhibits the enzyme cyclo-oxygenase, resulting in decreased formation of precursor of prostaglandins and thromboxanes from arachidonic acid. Although many of the therapeutic (and adverse) effects of these medications may result from inhibition of prostaglandin synthesis in various tissue, other actions may also contribute significantly to their therapeutic effects. In clinical studies in patients with rheumatoid arthritis and osteoarthritis, Ibuprofen has been shown to be comparable to Aspirin in controlling pain and inflammation and with a statistically significant reduction in the milder gastrointestinal side effects.

Pharmacokinetics:
Ibuprofen is rapidly absorbed when administered orally. Peak serum Ibuprofen levels are generally attained one to two hours after administration. Ibuprofen is rapidly metabolized and eliminated in the urine. The excretion is virtually complete 24 hours after the last dose. The serum half-life is 1.8 to 2.0 hours.

Product description:
YSP Ibuprofen Capsule 200mg:
A size #2 red cap and white body hard gelatine capsule, containing white powder.
YSP Ibuprofen Film Coated Tablet 400mg:
A white color elliptical film coated tablet, both sides impressed with a score  .

Indication(s):
Rheumatoid arthritis, osteoarthritis, relief of pain due to musculoskeletal inflammation.
Ibuprofen is also indicated for the treatment of primary dysmenorrhea.

Dosage and Administration:
Do not exceed 3200mg total daily dose. If gastrointestinal complaints occur, administer Ibuprofen with meals or milk.
Analgesic & antipyretic: 600 - 1200mg daily, in divided doses.
For rheumatoid arthritis and osteoarthritis: 1200 - 3200mg daily in divided doses. When treating patients with 3200mg/day, the physician should observe sufficient increased clinical benefit to offset potential increased risk. In general, patients with rheumatoid arthritis seem to require higher doses of Ibuprofen than patients with osteoarthritis.
Dysmenorrhea: 400mg every 4 hours when necessary for relief of pain.
A suggested dose for children:
20mg/kg body weight daily, in divided doses.
Not recommended for children under the age of 1 year or for children weighing less than 7kg. For short term use only.
After assessing the risk/ benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

Side Effect(s) / Adverse Reaction(s):
Gastrointestinal: Nausea, epigastric pain, heartburn, diarrhea.
Others: Dizziness, dyspepsia, headache, nervousness, pruritus, tinnitus, depression, insomnia, blurred vision and other ocular reactions.
Thrombocytopenia, agranulocytosis, hypersensitivity reaction, abnormalities of liver function test, impairment of renal function including interstitial nephritis or nephrotic syndrome.

Precaution(s) / Warning(s):
1. Should not be used in patients who have previously exhibited hypersensitivity to the drugs, or in individuals with the symptoms of nasal polyps, angioedema and bronchospastic reactivity to Aspirin or other non-steroidal anti-inflammatory agents.
2. 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.
3. 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.
4. 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.
5. Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.
6. 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.

7. Ibuprofen, like other non-steroidal anti-inflammatory agents, can inhibit platelet aggregation but the effect is less than that seen with Aspirin.
8. It should be used with caution in patients with intrinsic coagulation defects and those on anticoagulation therapy because Ibuprofen may prolong bleeding time.
9. May mask diagnostic signs in detecting complications of non-infectious non-inflammatory painful conditions.
10. Severe hepatic reactions have been reported with Ibuprofen as with other non-steroidal anti-inflammatory drugs. Discontinue use if liver disease develops.
11. Since Ibuprofen is eliminated primarily by the kidneys, patients with significantly impaired renal functions should be closely monitored.
12. Because of the known effects of non-steroidal anti-inflammatory drugs on the fetal cardiovascular system, use during late pregnancy should be avoided.

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, monitoring and supporting vital functions, and institution of symptomatic and other supportive treatment as needed. Induction of diuresis may be useful in overdoses with Ibuprofen.

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

Shelf-Life:
Plastic Bottle : 5 years from the date of manufacture.
Blister Pack : 3 years from the date of manufacture.

Packing(s):
Capsule (For Export Only):
Plastic bottle of 1000's and 1500's.
Blister packing of 10's x 10 and 10's x 100.
Tablet:
Plastic bottle of 500's, 1000's and 1500's (for export only).
Blister packing of 10's x 10 and 10's x 100.

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.

YSP IBUPROFEN

Penyampaian:
YSP Ibuprofen Kapsul 200mg:
Setiap kapsul mengandungi:
Ibuprofen 200mg
YSP Ibuprofen Tablet Bersalut Filem 400mg:
Setiap tablet mengandungi:
Ibuprofen 400mg

Indikasi:
Reumatoid artritis, osteoartritis, melegakan kesakitan dan sengal otot akibat inflamasi. Juga untuk rawatan dismenorea primer.

Dos:
1. Tidak melebihi 3200mg/hari. Jika ada gangguan perut, ambil bersama makanan atau susu.
2. Analgesik & antipiretik: 600 - 1200mg/hari, di dalam dos terbahagi.
3. Reumatoid arthritis dan osteoartritis: 1200 - 3200mg/hari. Jika dos 3200mg/hari diberi pesakit harus diperhatikan untuk kelebihan klinikal yang ketara berbanding dengan kemungkinan tambahan risiko kesan sampingan. Umumnya pesakit reumatoid artritis memerlukan dos yang lebih tinggi berbanding dengan pesakit osteoartritis.
4. Dismenorea: 400mg setiap 4 jam jika perlu, untuk melegakan kesakitan.
5. Kanak-kanak:-
   20mg/kg berat badan/hari di dalam dos terbahagi. Tidak disarankan untuk kanak-kanak di bawah umur 1 tahun atau berat badan kurang daripada 7kg. Untuk kegunaan jangka pendek sahaja.

Y. S. P.®
Manufacturer and Product Registration Holder:
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