Item Code	: 204032 - 07 draft 30 Jan 2023
PM Code	: Ins.P IDC
Measurement(mm) ± 2mm	: 260(L) x 110(W)
CURSOR (ATTACHMENT 1)	: L 156 - L158 mm
CURSOR (ATTACHMENT 2)	: T 078 - T082 mm
Colour of Artwork	: K 100
Source of Artwork	: MAC 3 / CC

INDOMEN CAPSULE

Ingredient(s):
Each capsule contains:
Indomethacin 25mg

Pharmacodynamics:
1. Indomethacin is a potent inhibitor of prostaglandin synthesis in vitro. Concentrations are reached during therapy which have been demonstrated to have an effect in vivo as well.Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin, inducing pain in animal models. Moreover, prostaglandins are known to be among the mediators of inflammation. Since Indomethacin is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.
2. Indomethacin has been shown to be an effective anti-inflammatory agent, appropriate for long term use in rheumatoid arthritis, ankylosing spondylitis, and osteoarthritis.
3. Indomethacin suppresses inflammation in rheumatoid arthritis as demonstrated by relief of pain, and reduction of fever, swelling and tenderness. Improvement in patients treated with Indomethacin for rheumatoid arthritis has been demonstrated by a reduction in joint swelling, average number of joints involved, and morning stiffness; by increasing mobility as demonstrated by a decrease in walking time; and by improving functional capability as demonstrated by an increase in grip strength.

Pharmacokinetics:
Indomethacin is readily absorbed from the gastrointestinal tract with peak plasma concentrations being reached about 2 hours after a dose. It has a half-life of about 4.5 hours and about 99 % is bound to plasma proteins. It is metabolized and undergoes enterohepatic circulation. Excretion of Indomethacin and metabolites as glucuronide conjugates, are predominantly in the urine with lesser amount appearing in the feces.

Indication(s):
Arthritis, Rheumatism, Arthritis deformans, and other inflammatory conditions.

Dosage and Administration:
Usual adult dose is 1 capsule 1 - 3 times daily.
The initial dose is 1 capsule 1 - 2 times daily, increased to 3 times daily for the first week.
For twice daily dosage, it should be taken in the morning and at bedtime.
After assessing the risk/ benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.
Its use is not recommended for children.
To be dispensed on doctor's prescription.

Route of administration:
Oral administration.

Precaution(s) / Warning(s):
1. Indomethacin should be administered with caution to patients with impaired renal function and to those with bleeding disorders, epilepsy, parkinsonism, or psychiatric disorders. It should not be given to patients with peptic ulcer or a history of gastrointestinal lesions or to those who are sensitive to Aspirin.
2. 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.
3. 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.
4. Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.
5. 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.
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. 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 upper GI problems (e.g. 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 GI events and other risk factors associated with peptic ulcer disease (e.g. 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.

Contraindication(s):
Indomethacin is contraindicated in patients who have shown hypersensitivity to this drug.

Side Effect(s) / Adverse Reaction(s):
The commonest adverse effects occurring with Indomethacin are gastrointestinal disturbances, headache, and dizziness. Gastrointestinal ulceration and bleeding may also occur. Other adverse effects include depression, drowsiness, tinnitus, confusion, lightheadedness, insomnia, psychiatric disturbances, syncope, convulsions, coma, peripheral neuropathy, blurred vision and other ocular effects, oedema and weight gain, hypertension, haematuria, skin rashes, pruritus, urticaria, stomatitis, alopecia, and hypersensitivity reactions. Leucopenia, purpura, thrombocytopenia, aplastic

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W
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anaemia, haemolytic anaemia, agranulocytosis, epistaxis, hyperglycaemia, hyperkalemia, and vaginal bleeding have been reported. There have also been reports of hepatitis and jaundice or renal failure. Hypersensitivity reactions may also occur in Aspirin-sensitive patients.

Symptoms and Treatment for Overdosage and Antidote(s):
The following symptoms may be observed following overdosage: nausea, vomiting, intense, headache, dizziness, mental confusion, disorientation, or lethargy. There have been reports of parasthesias, numbness and convulsion. Treatment is symptomatic and supportive. The stomach should be emptied as quickly as possible if the ingestion is recent. If vomiting has not occurred spontaneously, the patient should be induced to vomit with syrup of ipecac. If the patient unable to vomit, gastric lavage should be performed. Once the stomach has been emtied, 25 to 50g of activated charcoal may be given. Depending on the condition of the patient, close medical observation and nursing care should be required. The patients should be followed for several days because gastrointestinal ulceration and hemorrhage have been reported as adverse reactions of indomethacin. Use of antacids may be helpful.

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

Storage Condition(s):
Keep in a tight container. Store at temperature below 25ºC. Protect from light and moisture.
Keep medicine out of reach of children.

Product Description:
A size #2, light green cap, light yellow body hard gelatin capsule.

Packing(s):
Plastic container of 1000's and 1500's (for export only).
Blister packing of 10's x 10 and 10's x 50.

WARNINGS

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

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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.

INDOMEN KAPSUL

Bahan Aktif:
Setiap kapsul mengandungi:
Indomethacin 25mg

Indikasi:
Artritis, reumatisme, artritis deforman dan lain-lain keadaan radang.

Dos:
Dewasa: 1 kapsul 1 - 3 kali sehari. Dos permulaan, 1 kapsul 1 - 2 kali sehari.
Didispens mengikut preskripsi doktor.

Y. S. P.®

Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan, Malaysia.
Ordering Line:1 800 88 3027
Product Info: 1 800 88 3679

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