SPMC
INDOMETHACIN CAPSULES BP 25 mg

Presentation
1000'S capsules bulk pack. light Ivory / Black capsule "SPMC" logo and "SPMC" letters on the body and cap, each capsule contains 25 mg of Indomethacin BP.

INDICATIONS:
Indometacin has non-steroidal analgesic and anti-inflammatory properties. It is indicated for the following conditions:
• active stages of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, degenerative joint disease of the hip, acute musculoskeletal disorders, gout and lumbago.
• inflammation, pain and oedema following orthopaedic procedures.
• treatment of pain and associated symptoms of primary dysmenorrhoea.
Since indometacin is not a simple analgesic, its use should be limited to the above conditions.

DOSEGE:
Pain and moderate to severe inflammation in rheumatic disease and other musculoskeletal disorders
Adult: 50–200 mg daily in divided doses
Acute gout
Adult: 150–200 mg daily in divided doses
Dysmenorrhoea
Adult: Up to 75 mg daily

SIDE EFFECT:
GENERAL SIDE-EFFECTS
Agranulocytosis. alopecia.
anaphylactic reaction. angioedema. anxiety. Appetite decreased. arrhythmias. asthma. blood disorder. Bone marrow disorders. breast abnormalities. chest pain. Coma. confusion. congestive heart failure. constipation. corneal deposits. depression. diarrhea. disseminated intravascular coagulation. dizziness. drowsiness. dysarthria. erythema nodosum. Eye disorder. eye pain.fatigue. fluid retention. flushing. Gastrointestinal discomfort. gastrointestinal disorders. gynecomastia. haemolytic anaemia. haemorrhage. hallucination. headache. hearing impairment. hepatic disorders. hyperglycaemia. hyperhidrosis. hyperkalaemia. hypotension. inflammatory bowel disease. insomnia. leucopenia. movement disorders. muscle weakness. nausea. nephritis tubulointerstitial. nephrotic syndrome. oedema. Oral disorders. palpitations. pancreatitis. paresthesia. peripheral neuropathy. photosensitivity reaction. platelet aggregation inhibition. psychiatric disorders. renal failure (more common in patients with pre-existing renal impairment). respiratory disorders. seizures. severe cutaneous adverse reactions (SCARs). skin reactions. syncope. thrombocytopenia. tinnitus. urine abnormalities. vasculitis. vertigo. vision disorders. Vomiting

SPECIFIC SIDE-EFFECTS
With oral use Dyspnoea. malaise. pulmonary oedema. sigmoid lesion perforation

SIDE-EFFECTS, FURTHER INFORMATION For information about cardiovascular and gastrointestinal side-effects, and a possible exacerbation of symptoms in asthma,

CAUTION:
General cautions
Allergic disorders. cardiac impairment (NSAIDs may impair renal function). Cerebrovascular disease. coagulation defects. connective-tissue disorders. dehydration (risk of renal impairment). elderly (risk of serious side-effects and fatalities). epilepsy. heart failure. history of gastro-intestinal disorders (e.g., ulcerative colitis, Crohn's disease). ischaemic heart disease. parkinsonism. peripheral arterial disease. Psychiatric disturbances. risk factors for cardiovascular events. uncontrolled hypertension.

ALLERGY AND CROSS-SENSITIVITY:
Contra-indicated in patients with a history of hypersensitivity to aspirin or any other NSAID—which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID.

CONCEPTION AND CONTRACEPTION:
Caution—long-term use of some NSAIDs is associated with reduced female fertility, which is reversible on stopping treatment.

MONITORING REQUIREMENTS:
During prolonged therapy ophthalmic and blood examinations particularly advisable.

INTERACTIONS:
May diminish the antihypertensive effects of ACE inhibitors (e.g., captopril), β-blockers (e.g., propranolol, atenolol), diuretics (loop, K-sparing, thiazides), and angiotensin II receptor antagonists (e.g., losartan). Reduced clearance and increased the risk of toxicity of methotrexate and lithium. May increase plasma concentrations with probenecid. Increased serum concentrations of digoxin and aminoglycosides (e.g., amikacin, gentamicin). Increased risk of adverse effects with corticosteroids, antiplatelet agents (e.g., aspirin, clopidogrel), anticoagulants (e.g., warfarin), SSRIs, and other NSAIDs. May enhance the effect of desmopressin. Enhanced drowsiness with haloperidol. May reduce the effect of mifepristone. Indometacin may enhance the nephrotoxic effects of ciclosporin, tacrolimus and triamterene. Increased bioavailability of tiludronic acid. May enhance the seizure-potentiating adverse effect of quinolones.
Potentially Fatal: Decreased renal clearance and increased plasma concentration with diflunisal.

PREGNANCY:
Avoid unless the potential benefit outweighs
the risk. Avoid during the third trimester (risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn); onset of labour
may be delayed and duration may be increased.

BREAST FEEDING:
Amount probably too small to be harmful—manufacturers advise avoid. Use with caution during breast-feeding.

HEPATIC IMPAIRMENT:
Use with caution; there is an increased risk of gastro-intestinal bleeding and fluid retention. Avoid in severe liver disease.

RENAL IMPAIRMENT:
Avoid if possible or use with caution. Avoid in severe impairment. Dose adjustments the lowest effective dose should be used for the shortest possible duration. Monitoring In renal impairment monitor renal function; sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure.

PATIENT AND CARER ADVICE:
Driving and skilled tasks Dizziness may affect performance of skilled tasks (e.g., driving).

CONTRA INDICATION:
Active gastro-intestinal bleeding. active gastro-intestinal ulceration. history of gastrointestinal bleeding related to previous NSAID therapy. history of gastro-intestinal perforation related to previous NSAID therapy. history of recurrent gastro-intestinal haemorrhage (two or more distinct episodes). history of recurrent gastro-intestinal ulceration (two or more distinct episodes). severe heart failure.

OVERDOSAGE:
a) Symptoms:

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions, abdominal pain, anorexia, restlessness and agitation. In cases of significant poisoning acute renal failure and liver damage are possible.

b) Therapeutic measure

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

STORAGE:
Keep a cool & dry place. Store below 30°C in the original package in order to protect from moisture & Light**. Keep all medicines away from children.**

Manufactured by
State Pharmaceuticals Manufacturing Corporation
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Sri Lanka.