SPMC
ASPIRIN GASTRO- RESISTANCE TABLETS BP 75 mg

PRESENTATION:
Aspirin Gastro-Resistant tablets BP 75 mg,
Bulk pack -500 & 100 tablets,
Each white, circular, biconvex Enteric film coated tablets of 6.3 mm diameter contain Aspirin 75 mg.

INDICATIONS AND DOSE:
Cardiovascular disease (secondary prevention)
Adult: 75 mg daily
Management of unstable angina and non-ST-segment elevation myocardial infarction (NSTEMI) Management of ST-segment elevation myocardial infarction (STEMI)
Adult: 300 mg, chewed or dispersed in water
Suspected transient ischaemic attack
Adult: 300 mg once daily until diagnosis established
Transient ischaemic attack (long-term treatment in combination with dipyridamole) | Ischaemic stroke not associated with atrial fibrillation (in combination with dipyridamole if clopidogrel contra-indicated or not tolerated) | Ischaemic stroke not associated with atrial fibrillation (used alone if clopidogrel and dipyridamole contra-indicated or not tolerated)
Adult: 75 mg once daily
Acute ischaemic stroke
Adult: 300 mg once daily for 14 days, to be initiated 24 hours after thrombolysis or as soon as possible within 48 hours of symptom onset in patients not receiving thrombolysis
Atrial fibrillation following a disabling ischaemic stroke before being considered for anticoagulant treatment)
Adult: 300 mg once daily for 14 days
Following disabling ischaemic stroke in patients receiving anticoagulation for a prosthetic heart valve and who are at significant risk of haemorrhagic transformation
Adult: 300 mg once daily, anticoagulant treatment stopped for 7 days and to be substituted with aspirin
Following coronary by-pass surgery
Adult: 75–300 mg daily
Mild to moderate pain | Pyrexia
Adult: 300–900 mg every 4–6 hours as required; maximum 4 g per day
Acute migraine
Adult: 900 mg for 1 dose, to be taken as soon as migraine symptoms develop.
Prevention of pre-eclampsia in women at moderate or high risk
Adult: 75–150 mg once daily from 12 weeks gestation until the birth of the baby.
Mild to moderate pain (dose approved for use by community practitioner nurse prescribers) | Pyrexia (dose approved for use by community practitioner nurse prescribers)
Child 16–17 years: 300–600 mg every 4–6 hours as required, maximum 2.4 g per day without doctor's advice
Adult: 300–600 mg every 4–6 hours as required, maximum 2.4 g per day without doctor's advice

SIDE EFFECTS:
GENERAL SIDE-EFFECTS
▸***Rare or very rare***
Asthmatic attack . bronchospasm

SPECIFIC SIDE-EFFECTS
▸***Common or very common***
With oral use Dyspepsia . haemorrhage
▸***Uncommon***
With oral use Dyspnoea . rhinitis . severe cutaneous adverse reactions (SCARs) . skin reactions
▸***Rare or very rare***
With oral use Aplastic anaemia . erythema nodosum .gastrointestinal haemorrhage (severe) . granulocytosis .haemorrhagic vasculitis . intracranial haemorrhage . menorrhagia . nausea . thrombocytopenia . vomiting
▸***Frequency not known***
With oral use Fluid retention . gastrointestinal disorders headache . hearing loss . hepatic failure . hyperuricaemia . iron deficiency anaemia . renal impairment . sodium retention tinnitus . vertigo

HEPATIC IMPAIRMENT:
Manufacturer advises use with caution in mild-to-moderate impairment; avoid in severe impairment.

RENAL IMPAIRMENT:
Use with caution; avoid in severe impairment; sodium and water retention; deterioration in
renal function; increased risk of gastro-intestinal bleeding.

CAUTIONS:
Allergic disease . anaemia . asthma .
dehydration. elderly . G6PD deficiency . preferably avoid during fever or viral infection in children (risk of Reye's syndrome) previous peptic ulceration (but manufacturers may advise avoidance of low-dose aspirin in history of peptic ulceration) thyrotoxicosis uncontrolled hypertension

CAUTIONS, FURTHER INFORMATION:
Elderly Prescription potentially inappropriate (STOPP criteria): at long-term doses greater than 160mg daily (increased risk of bleeding, no evidence for increased efficacy)with a past history of peptic ulcer disease without concomitant proton pump inhibitor use (risk of recurrent peptic ulcer) with concurrent significant bleeding risk, such as uncontrolled severe hypertension, bleeding diathesis or recent non-trivial spontaneous bleeding (high risk of bleeding) when used with clopidogrel as secondary stroke prevention unless the patient has a coronary stent(s) inserted in the previous 12 months, or concurrent acute coronary syndrome, or has a high grade symptomatic carotid arterial stenosis (no evidence of added benefit over clopidogrel monotherapy) when used with vitamin K antagonists, direct thrombin inhibitors or factor Xa inhibitors in patients with chronic atrial fibrillation (no added benefit from aspirin)

CONTRAINDICATION:
Active peptic ulceration . bleeding disorders . children under 16 years (risk of Reye's syndrome) . haemophilia previous peptic ulceration (analgesic dose). severe cardiac failure (analgesic dose).

CONTRA-INDICATIONS, FURTHER INFORMATION:-
Reye's syndrome Owing to an association with Reye's syndrome, manufacturer advises aspirin-containing preparations should not be given to children under 16 years, unless specifically indicated, e.g. for Kawasaki disease.

PREGNANCY:
Use antiplatelet doses with caution during third trimester; impaired platelet function and risk of haemorrhage; delayed onset and increased duration of labour with increased blood loss; avoid analgesic doses if possible in last few weeks (low doses probably not harmful); high doses may be related to intra-uterine growth restriction, teratogenic effects, closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of newborn; kernicterus may occur in jaundiced neonates.

BREASTFEEDING:
Avoid—possible risk of Reye's syndrome; regular use of high doses could impair platelet function and produce hypoprothrombinaemia in infant if neonatal vitamin K stores low.

PRESCRIBING AND DISPENSING INFORMATION:-
In adults BP directs that when no strength is stated the 300mg strength should be dispensed, and that when soluble aspirin tablets are prescribed, dispersible aspirin tablets shall be dispensed.

DRUG INTERACTIONS:
Increased risk of GI bleeding and ulceration with corticosteroids. Increased risk of bleeding with coumarin anticoagulants (e.g. heparin, warfarin, phenindione) and antiplatelet agents (e.g. clopidogrel, dipyridamole). May result in severe acidosis and increased CNS toxicity with carbonic anhydrase inhibitors (e.g. acetazolamide). Increases the hypoglycaemic effect of sulfonylureas. Reduces binding of phenytoin and valproate to serum albumin leading to increased free concentration of the drugs. Reduces the effect of uricosurics (e.g. probenecid, sulfinpyrazone). Impairs the renal excretion of lithium and digoxin.
Potentially Fatal: Increased risk of GI bleeding and ulceration with other NSAIDs. Increased risk of haematological toxicity of methotrexate.

OVERDOSAGE:
The main features of salicylate poisoning are hyperventilation, tinnitus, deafness, vasodilatation, and sweating. Coma is uncommon but indicates very severe poisoning. For specific details on the management of poisoning, see Aspirin, under Emergency treatment of poisoning.

ALLERGY AND CROSS-SENSITIVITY:
Aspirin is contraindicated in 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.

STORAGE:
Keep tightly closed in a dry place at a temperature not exceeding 30 ^{0}C. Keep all the medicines away from the reach of children

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No.11, Sir Jone Kotalawala Mawatha,
Kadawala Estate,
Ratmalana, Sri Lanka.