Primera

ASPIRIN
ASAPRIM

℞

100 mg Enteric-Coated Tablet
PLATELET AGGREGATION INHIBITOR (SALICYLIC ACID DERIVATIVE)

FORMULATION:
Each tablet contains:
Aspirin,USP……100 mg

DESCRIPTION:
Aspirin (Asaprim) is a violet to bluish-violet enteric coated tablet, biconvex and plain on both sides.

CLINICAL PHARMACOLOGY:
PHARMACODYNAMICS:
Aspirin is used for pain, fever, inflammation and the prevention of myocardial infarction and stroke. The antithrombotic activity of aspirin is due to its inhibitory effect on platelets which is mediated via irreversible acetylation of platelet cyclooxygenase with subsequent blockade of platelet thromboxane synthesis. The inhibitory effect of aspirin on platelet thromboxane production persists for the lifespan of the platelet, around 7 to 10 days. As a result, acetylation of platelet cyclooxygenase and consequent inhibition of thromboxane formation is cumulative on repeated dosing. Low doses of aspirin inhibit platelet aggregation and may be more effective than higher doses. Larger doses inhibit cyclooxygenase in arterial walls, interfering with prostacyclin production, a potent vasodilator and consequent inhibition of platelet aggregation.

PHARMACOKINETICS:
About 80% to 100% of an oral dose of aspirin is absorbed from the gastrointestinal tract. However, the actual bioavailability of the drug as unhydrolyzed aspirin is lower since aspirin is partially hydrolyzed to salicylate in the gastrointestinal mucosa during absorption and on first pass through the liver. Food does not appear to decrease the bioavailability of unhydrolyzed aspirin; however, absorption is delayed and peak serum aspirin concentration may be decreased. Aspirin is rapidly and widely distributed into most body tissues and fluids. Aspirin's volume of distribution is 0.15 to 0.2 L/kg. Aspirin is poorly bound to plasma proteins; the unhydrolyzed drug is 33% bound at a serum salicylate concentration of 120 mcg/mL.

INDICATIONS:
- ***For primary prevention of thromboembolic disorders and cardiovascular events:***
  - Chronic stable angina pectoris
  - Unstable angina pectoris
  - Prevention of recurrent MI
  - Acute myocardial infarction (MI)
  - Ischemic stroke
  - Transient ischemic attack (TIA)
- ***For secondary prevention of cardiovascular disease in persons with diabetes mellitus especially in the following subgroups.***
  - History of myocardial infarction (MI), vascular bypass procedure, stroke or transient ischemic attack, and angina.
  - Persons with additional risk factors: hypertension, smoking, dyslipidemia, and family history of cardiovascular disease.
- ***Pregnancy-induced hypertension***

For primary prevention of pregnancy-induced hypertension, preeclampsia and intrauterine growth retardation particularly in pregnant women with pre-existing chronic hypertension, auto-immune disorders like systemic lupus erythematosus (SLE), positive cardiolipin antibody test, history of recurring toxemia in successive pregnancies, and hypotension developing before the 20th week of gestation.
- ***Revascularization procedures***

For patients who have undergone revascularization procedures such as corona artery bypass graft (CABG), percutaneous transluminal coronary angioplasty (PTCA), and carotid endarterectomy when there is a pre-existing condition for which aspirin is already indicated.

DOSAGE AND ADMINISTRATION:
Take one dose of Aspirin (Asaprim) with a full glass of water unless patient is fluid restricted.

INDICATIONS	INITIAL ADULT DOSE	MAINTENANCE ADULT DOSE
Prevention of myocardial infarction (MI) and stroke	75 mg to 100 mg once daily	Continue therapy indefinitely
Prevention of Recurrent myocardial infarction (MI)	75 mg to 325 mg once daily	Continue therapy indefinitely
Ischemic stroke and TIA	50 mg to 325 mg once daily	Continue therapy indefinitely
Suspected acute myocardial infarction (MI)	160 mg as soon as MI is suspected	160 mg once daily for 30 days post MI; after 30 days, consider further therapy based on dosage for prevention of recurrent MI
Unstable angina pectoris and chronic stable angina pectoris	75 mg to 325 mg once daily	Continue therapy indefinitely
Primary and secondary prevention of Cardiovascular events in patients with Type 1 and Type 2 diabetes mellitus	75 mg to 325 mg once daily	Continue therapy indefinitely
Coronary Artery Bypass	325 mg once daily starting 6 hours post-procedure	Continue therapy for 1 year post-procedure
Percutaneous Transluminal Coronary Angioplasty (PTCA)	325 mg given 2 hours pre-angioplasty 160 mg to 325 mg once daily	Continue therapy indefinitely
Carotid endarterectomy	80 mg once daily to 650 mg twice daily, started pre-surgery	Continue therapy indefinitely
Prevention of Complications of Pregnancy • Pregnancy induced hypertension • Preeclampsia • Intrauterine growth retardation • Pregnancy with existing conditions (e.g., SLE, positive cardiolipin antibody)	80 mg daily from 13th to 26th weeks of gestation	

CONTRAINDICATIONS:
Known hypersensitivity to Aspirin
Patients with asthma, rhinitis and nasal polyps. Aspirin may cause severe urticaria, angioedema or bronchospasm.
Avoid use in children or teenagers for viral infections, with or without fever, because of the risk of Reye's syndrome with concomitant use of Aspirin in certain viral illness.

WARNINGS AND PRECAUTIONS:
Aspirin should be used cautiously, if at all, in patients prone to dyspepsia or known to have lesion of the gastric mucosa. It should not be administered to patients with hemophilia or other hemorrhagic disorders, to patients with gout, or to those with an intolerance to aspirin (esp. aspirin sensitive asthmatics). Caution is necessary when renal or hepatic function is impaired. The use of aspirin in children under the age of 12 years is extremely limited because of the risk of Reye's syndrome. Mothers who are breast feeding their infants should not take aspirin.

PREGNANCY AND LACTATION:
Pregnant women should only take aspirin if clearly needed. Avoid use during the third trimester of pregnancy because of aspirin's known effect on the fetal cardiovascular system (i.e., closure of ductus arteriosus).
Breast feeding mothers should avoid using aspirin because salicylate is excreted via breast milk. Use of high doses may lead to rashes, platelet abnormalities and bleeding in breastfed infants.

INTERACTIONS:
Uricosuric agents (Probenecid, Sulfinpyrazone): Salicylates antagonize the uricosuric action of these agents.
Oral hypoglycemics: Moderate doses of aspirin may increase the effectiveness of oral hypoglycemic drugs, leading to hypoglycemia
NSAIDs: Increased bleeding or may lead to decreased renal function
Methotrexate: Salicylate may inhibit renal clearance of methotrexate, leading to bone marrow toxicity, especially in the elderly or renal impaired
Diuretics: Decreased effectiveness of diuretics in patients with underlying renal or cardiovascular disease due to inhibition of renal prostaglandins, leading to decreased renal blood flow and fluid retention
Beta-Blockers: Decreased hypotensive effects of beta-blockers due to inhibition of renal prostaglandins, leading to decreased renal blood flow, and salt and fluid retention
Anticonvulsants: Salicylate can displace protein-bound phenytoin and valproic acid, leading to decreased total concentrations of phenytoin and increased serum acid levels of valproic acid
Anticoagulant therapy (Heparin, Warfarin): Increased risk of bleeding because of drug-drug interactions and the effects on platelets
Acetazolamide: Increased in serum acetazolamide concentrations and toxicity due to competition at the renal tubule for secretion
Angiotensin Converting Enzyme Inhibitors (ACEIs): Hyponatremic and hypotensive effects of ACE inhibitors may be decreased

ADVERSE DRUG REACTIONS:
The most common adverse effects occurring with therapeutic doses of aspirin are gastrointestinal disturbances such as nausea, dyspepsia and vomiting. Aspirin may provoke various reactions including urticaria and other skin eruptions, angioedema, rhinitis and fatal paroxysmal bronchospasm and dyspnea, especially to those with asthma, chronic urticaria or chronic rhinitis. Aspirin increases bleeding time, decreases platelet adhesiveness and, in larger doses, may cause hypoprothrombinemia. Persons sensitive to aspirin may exhibit cross-sensitivity to other NSAIDs. Symptoms of salicylism include dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache and mental confusion. In children, the use of aspirin has been implicated in cases of Reye's syndrome.

OVERDOSAGE AND TREATMENT:
Salicylate over dosage resulting from acute ingestion of aspirin, little or no toxicity generally occurs in individuals ingesting less than 150 mg/kg, mild to moderate toxicity in those ingesting 150 to 300 mg/kg, severe toxicity in those ingesting 300 to 500 mg, and potentially lethal toxicity in those ingesting greater than 500 mg/kg. A single lethal dose of aspirin in adults is not known with certainty but death may be expected at 30 grams.

The principal toxic effects of salicylate over dosage are extension of pharmacologic actions and include local gastrointestinal irritation, direct central nervous system simulation of respiration, severe acid-base and electrolyte disturbances and are complicated by hyperthermia and dehydration. Respiratory alkalosis occurs early while hyperventilation is present, but is quickly followed by metabolic acidosis.

Treatment consists primarily of supporting vital functions, increasing salicylate elimination, and correcting the acid-base disturbance. Gastric emptying and/or lavage is recommended as soon as possible after ingestion, even if the patient has vomited spontaneously. After lavage and/or emesis, administration of activated charcoal (as slurry), is beneficial, if less than 3 hours have passed after ingestion. Charcoal absorption should not be employed prior to emesis and lavage.

Severity of aspirin intoxication is determined by measuring the blood salicylate level. Acid base status should be closely followed with serial blood gas and serum pH measurements. Fluid and electrolyte balance should be maintained.
Hemodialysis and peritoneal dialysis may be performed to reduce the body drug content. Dialysis is usually required in patients with renal insufficiency or in cases of life-threatening intoxication.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.
Store in an airtight container

AVAILABILITY:
Blister Pack x 10's (Box of 100's)

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING STATEMENT:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

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