

New Zealand Data Sheet

Ecotrin (This medicine is not currently marketed in New Zealand)

Aspirin

Presentation

Round, biconvex, yellow-orange enteric coated tablets, approximately 12.9 mm in diameter. Each enteric-coated tablet contains 650 mg aspirin.

Clinical Particulars

Therapeutic indications

Ecotrin is indicated for long term relief of pain in rheumatoid arthritis; osteoarthritis; any rheumatic disease where long term analgesia and anti-inflammatory effect is required; acute rheumatic fever.

The delay in absorption makes it unsuitable for conditions such as headache where rapid absorption is required. In arthritic and rheumatic conditions, concomitant use of Ecotrin often permits a reduction in steroid dosage.

Posology and method of administration

The usual adult dosage is 1-2 tablets, 3-4 times daily taken with food. Ecotrin tablets must be swallowed whole with water without crushing.

Dosage should be minimised in the elderly and in patients with renal impairment.

High aspirin dosage is recommended in arthritic and rheumatic conditions. The dose required for measurable anti-inflammatory effect in rheumatic diseases is that which results in sustained plasma salicylate concentrations of 15-30 mg%; usually 2.6-6.5 g daily (4-10 x 650 mg tablets) on a divided dosage schedule. Plasma salicylate determinations are recommended for dose guidance. Rheumatic fever may require a plasma concentration of 25-35 mg% for significant effect. Older patients tend to experience tinnitus or deafness well below 30 mg%.

Contraindications

Ecotrin is contraindicated in patients with gastrointestinal ulceration, haemorrhagic diathesis and asthma.

Other contraindications include:

- Aspirin hypersensitivity manifested for example as anaphylaxis or angioneurotic oedema.
- Bleeding disorders such as haemophilia and Von Willebrand's disease.
- Not recommended for use in children.

Relatively contraindicated in liver dysfunction.

Special warnings and special precautions for use

Ecotrin should not be administered simultaneously with other salicylate-containing preparations, uricosuric agents or non-steroidal anti-inflammatory drugs.

Aspirin should be administered with care to patients with bronchial asthma or a history of peptic ulceration.

Use with caution in the presence of bleeding tendencies or anticoagulant therapy. It may be advisable to withdraw aspirin one week prior to surgery. Blood donors should cease all forms of aspirin one week prior to blood donation.

Tinnitus is a premonitory sign of salicylism but may not be detected in patients with hearing loss.

Special care is needed in patients with renal/hepatic impairment.

Interaction with other medicaments and other forms of interaction

Aspirin, because of its effect on platelets, should be avoided in patients using oral anticoagulants or heparin, unless indicated. Care should be observed when co-administering aspirin and methotrexate, chlorpropamide, corticosteroids, sulphinpyrazone, probenecid and spironolactone.

Interference with clinical and laboratory tests:-

- Heparin activity. Decreased platelet activity caused by aspirin may exaggerate heparin activity tests such as Lee-White clotting time and activated partial thromboplastin time.
- Urinary glucose oxidase. Aspirin may cause a false negative test in the presence of glycosuria.

Pregnancy and lactation

Animal studies have shown that aspirin can cause birth defects in numerous species. There is no conclusive evidence that aspirin causes malformations in humans. Medicines such as aspirin with peripheral inhibitory effect on prostaglandin synthesis, when given during the latter part of pregnancy, may cause premature closure of the foetal ductus arteriosus in animal experiments. When given at term, they prolong labour and delay parturition. There is evidence that this also applies to humans. Intake of aspirin increases the bleeding tendency both in the newborn child and in the mother. Products containing aspirin should be avoided in late pregnancy.

Aspirin passes into breast milk.

Effects on ability to drive and use machines

Not applicable.

Undesirable effects

Side effects of aspirin are mainly gastrointestinal including heartburn, nausea, bleeding and activation of peptic ulcer.

Aspirin has also been associated with hypoprothrombinaemia, itching, rashes, urticaria, dermatitis and thrombocytopaenia.

Asthma, vasomotor rhinitis, urticaria and angioneurotic oedema are common manifestations of aspirin sensitivity but other skin reactions, eg. erythema and pustular eruptions have also been described.

Low doses of aspirin have been reported to cause a retention of uric acid, whereas high dosage may increase excretion.

Other possible adverse events associated with high aspirin dosage include dizziness, tinnitus, vertigo and deafness.

Overdose

Symptoms

Symptoms are those of salicylate intoxication. In mild overdosage, these may include rapid and deep breathing, nausea, vomiting, vertigo, tinnitus, flushing, sweating, thirst and tachycardia. Severe cases may show fever, haemorrhage, excitement, confusion, convulsions or coma, respiratory failure.

Treatment

Gastric lavage or emesis and force fluids, eg. salty broth to replace sodium loss. If patient is unable to retain fluids orally, infuse saline or sodium bicarbonate depending on electrolytes and pH. Sodium bicarbonate will increase renal excretion of salicylate.

Treat severe excitement of convulsions with a barbiturate. In severe cases dialysis should be considered.

Pharmacological Properties

Actions

Ecotrin tablets are formulated to provide adequate dosage of aspirin in patients who cannot tolerate conventional aspirin tablets; also offering fewer tablets each day. Because the contents of Ecotrin are released in the alkaline, enzymatic milieu of the small intestine, irritation of the gastric mucosa and the risk of gastrointestinal haemorrhage is reduced.

Pharmacology

The mechanism by which aspirin relieves pain and reduces inflammation is incompletely determined, but there is evidence for an action at the site of pain origin. In addition to its analgesic, anti-inflammatory and antipyretic properties, aspirin in high doses may cause an increase in the rate and depth of respiration, nausea and vomiting and aural effects of salicylism. Single doses of aspirin may prolong bleeding time slightly, due to inhibition of platelet aggregation or adhesion. Salicylates, depending on the formulation used, are absorbed rapidly and completely from the stomach and small intestine and distributed to all body tissues. Plasma salicylate levels of approximately 15-20 mg per 100 mL are required for optimum anti-inflammatory results in patients with rheumatoid arthritis.

Pharmaceutical Particulars

Shelf Life

2 years when stored below 30°C.

Medicine Classification

Restricted Medicine

Package Quantities

Blister packs of 100 tablets.

Name and Address

Boucher & Muir (New Zealand) Ltd t/a Goldshield Healthcare (New Zealand)
39 Anzac Road
Browns Bay
Auckland 0753

Ph: 0800 437 849

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24 May 2004

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