Sulidac®

Sulindac BP Tablet

DESCRIPTION

Sulidac® is a preparation of Sulindac. It is a non-steroidal, antirheumatic agent with anti-inflammatory, analgesic and antipyretic properties. Prostaglandin synthetase inhibition has been hypothesised to be the mechanism of action of non-steroidal anti-inflammatory agents. Following absorption, **Sulidac®** undergoes two major biotransformations: reversible reduction to the sulphide metabolite, and irreversible oxidation to the inactive sulphone metabolite. The sulphide metabolite is a potent inhibitor of prostaglandin synthesis.

INDICATIONS

Sulidac® is indicated in the treatment of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis, peri-articular disorders such as bursitis, tendinitis, and tenosynovitis.

The anti-tumor activity of Sulindac has been demonstrated in patients with polyposis coli. 3 months treatment with Sulindac decrease polyp number to 45% of baseline & polyp size to 50% of baseline.

DOSAGE AND ADMINISTRATION

Sulidac® is usually given in a dose of 100-200 mg twice daily and is taken with fluids or food.

The usual dosage is 400 mg a day. However, the dosage may be lowered depending on the response.

Doses above 400 mg per day are not recommended.

In the treatment of acute gouty arthritis, therapy for seven days is usually adequate.

In periarticular disorders, treatment should be limited to seven to ten days.

Children: The use of **Sulidac®** in children is not recommended.

Use in the elderly: The dosage does not require modification for the elderly patient.

CONTRAINDICATION

Sulindac is contraindicated in patients who are hypersensitive to Sulindac or any component of this product.

The use of Sulindac is contra-indicated in patients with hepatic insufficiency.

Sulindac should not be used in patients in whom acute asthmatic attacks, urticaria or rhinitis have been precipitated by aspirin or other non-steroidal anti-inflammatory agents.

The drug should not be administered to patients with active gastro-intestinal bleeding. The use of Sulindac should be avoided in patients with active peptic ulcer.

USE IN PREGNANCY AND LACTATION

Use in pregnancy

Sulindac should be used during the first two trimesters of pregnancy only if the potential benefit justifies the potential risk to the fetus. The known effects of drugs of this class on the human fetus during the third trimester of pregnancy include: constriction of the ductus arteriosus prenatally, tricuspid incompetence, and pulmonary hypertension, non-closure of the ductus arteriosus postnatally which may be resistant to medical management. Use of sulindac during the third trimester of pregnancy is not recommended.

Use in lactation

It is not known whether Sulindac is excreted in human milk. Because other drugs of this class are excreted in human milk, a decision should be made whether to discontinue breast-feeding or discontinue the drug, taking into account the importance of the drug to the mother.

SIDE-EFFECTS

Sulidac® is generally well tolerated. Those side effects experienced are usually mild and may often respond to a reduction in dosage.

Side effects that may reported frequently includes-

Gastro-intestinal: Gastro-intestinal pain, dyspepsia, nausea with or without vomiting, diarrhoea, constipation, flatulence, anorexia, and gastro-intestinal cramps.

Dermatological: rash, pruritus.

Central nervous system: dizziness, headache, nervousness.

Others: tinnitus, oedema.

DRUG INTERACTIONS

Dimethyl sulphoxide :

Dimethyl sulphoxide should not be used with Sulindac. Concomitant use has been reported to reduce plasma levels of the active metabolite of Sulindac and also cause peripheral neuropathy.

Methotrexate :

Caution should be used if Sulindac is administered concomitantly with methotrexate. Non-steroidal anti-inflammatory drugs have been reported to decrease the tubular secretion of methotrexate and potentiate the toxicity.

Cyclosporin :

Administration of non-steroidal anti-inflammatory drugs concomitantly with cyclosporin has been associated with an increase in cyclosporin-induced toxicity, possibly due to the decreased synthesis of renal prostacyclin. NSAIDs should be used with caution in patients taking cyclosporin, and renal function should be monitored carefully.

Oral anticoagulants and hypoglycaemic agents :

Although Sulindac and its sulphide metabolite are highly bound to protein, studies have shown no clinically significant interaction with oral anticoagulants or oral hypoglycaemic agents. However, patients should be monitored carefully until it is certain that no change in their anticoagulant or hypoglycaemic dose is required.

Aspirin :

Concomitant administration with aspirin in normal volunteers significantly depressed plasma levels of the active sulphide metabolite. Clinical study of the combination showed an increase in GI side effects with no improvement in the therapeutic response to sulindac. The combination is not recommended.

Other NSAIDS :

The concomitant use of Sulindac with other NSAIDs is not recommended due to the increased possibility of gastro-intestinal toxicity, with little or no increase in efficacy.

Probenecid :

Probenecid given concomitantly with Sulindac had only a slight effect on plasma sulphide levels, while plasma levels of Sulindac and sulphone were increased. Sulindac was shown to produce a modest reduction in the uricosuric action of probenecid which probably is not usually significant.

Dextropropoxyphene hydrochloride/paracetamol :

Neither dextropropoxyphene hydrochloride nor paracetamol had any effect on the plasma levels of Sulindac or its sulphide metabolite.

Antacids :

In a drug interaction study, an antacid (magnesium and aluminium hydroxides in suspension) was administered with Sulindac with no significant difference in absorption.

Antihypertensive agents :

In contrast to most other non-steroidal anti-inflammatory drugs, Sulindac does not reduce the antihypertensive effect of thiazides and a variety of other agents used to treat mild to moderate hypertension. However, the blood pressure of patients taking Sulindac with antihypertensive agents should be closely monitored.

OVERDOSAGE

Cases of overdosage have been reported and, rarely, fatalities have occurred. The following signs and symptoms may be observed following overdosage: stupor, coma, diminished urine output and hypotension. In isolated cases patients have received up to 600 mg a day without adverse consequences being reported. In the event of acute overdosage, if ingestion is recent, the stomach should be emptied by inducing vomiting or by gastric lavage, and the patient carefully observed and given symptomatic and supportive treatment.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Sulidac® 100 Tablet:	Box containing 5 strips of 10 tablets each. Each tablet contains Sulindac BP 100 mg.
Sulidac® 200 Tablet:	Box containing 2 strips of 10 tablets each. Each tablet contains Sulindac BP 200 mg.

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Manufactured by

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