RUFENAC 100 SR

(Prolonged Release Diclofenac Tablets BP)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

RUFENAC 100 SR (Prolonged Release Diclofenac Tablets BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Name of constituent	Quantity per tablet in mg
1	Diclofenac Sodium BP	100.0
2	Lactose BP	110.50
3	Maize Starch BP	2.50
4	Hydroxypropyl Methyl cellulose USP (Methocel K4 M Premium)	40.00
5	Hydroxypropyl Methyl cellulose USP (Methocel K15 M Premium)	30.00
6	Colloidal Anhydrous Silica BP	4.50
7	Purified Talc BP	6.50
8	Magnesium Stearate BP	6.00
9	Instacoat Universal (A05R02687)* Pink (Mixture of Lake Erythrosine, Red Iron Oxide, Black Iron Oxide & Titanium Dioxide)	8.00

Definitions:

USP: United States Pharmacopoeia

BP: British Pharmacopoeia

IH: In House Specification

3. PHARMACEUTICAL FORM

Tablet (Oral)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Diclofenac sodium is a non-steroidal anti-inflammatory drug (NSAID) recommended for the treatment of :Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis, acute gout, low back pain, in the relief of pain in fractures, acute musculo-skeletal disorders and trauma including periarthritis (particularly frozen shoulder), bursitis, tendinitis, tenosynovitis, dislocations, sprains and strains, in the control of pain and inflammation in orthopaedic, dental and other minor surgery.

4.2 Posology and method of administration

Route of Administration: Oral

Dosage Recommendations: Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. Adults: One 100 mg tablet to be taken once a day swallowed whole, preferably with or after food. Children: Diclofenac sodium is not suitable for use in children. The Elderly: The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

4.3 Contraindications

Hypersensitivity to diclofenac sodium or to any of the excipients Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g., asthma, rhinitis, angioedema, urticaria), in response to aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs.

Porphyria.

Severe heart failure, hepatic failure and renal failure. During the last trimester of pregnancy. History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

4.4 Special warnings and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.The use of Diclofenac with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. Elderly : The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal .

Respiratory disorders : Caution is required if administered to patients suffering from, or with a previous history of bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients. Cardiovascular, Renal and Hepatic Impairment: The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly.

Monitoring of renal function, hepatic function (elevation of liver enzymes may occur) and blood counts should be performed on long-term NSAID patients, as a precautionary measure. Cardiovascular and cerebrovascular effects: Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy. Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking should only be treated with diclofenac after careful consideration. As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

Gastrointestinal bleeding, ulceration and perforation: GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk. When GI bleeding or ulceration occurs in patients receiving diclofenac, the treatment should be withdrawn.

Impaired female fertility: The use of diclofenac may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of diclofenac should be considered.

Pregnancy and Lactation: In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of the ductus arteriosus), use in the last trimester is contraindicated. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child.

NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

Effects on ability to drive and operate machinery: Undesirable effects such as dizziness, drowsiness, fatigue, visual disturbances and headaches are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.5 Interaction with other medicinal products and other forms of interaction

Care should be taken in patients treated with any of the drugs mentioned below because, as with other NSAIDs, diclofenac sodium has the potential to induce the following interactions.

Other analgesics including cyclooxygenase-2 selective inhibitors

Avoid concomitant use of two or more NSAIDs (including aspirin). Anti-hypertensives: Reduced anti-hypertensive effect. Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs. Cardiac Glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels. Lithium: Decreased elimination of lithium. Methotrexate: Decreased elimination of methotrexate. Ciclosporin: Increased risk of nephrotoxicity. Quinolone Antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Anticoagulants: Care is required when giving anticoagulants with NSAIDs as diclofenac may reversibly inhibit platelet aggregation. NSAIDs may enhance the effects of anti-coagulants, such as warfarin. Monitoring is recommended to ensure the desired response to the anticoagulants is maintained. Oral Hypoglycaemic Agents: It has been reported that hypo- and hyperglycaemic effects have occurred rarely when diclofenac and oral antidiabetic agents have been given together and adjustment of the hypoglycaemic may be required. Inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased risk of hypoglycaemia have also been reported. Aminoglycosides: Reduction in renal function in susceptible individuals, Probenecid. Reduction in metabolism and elimination of NSAID and metabolites occurs with probenecid. Mifepristone: NSAIDs should not be used for 8 to 12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone. Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding. Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs) Increased risk of gastrointestinal bleeding. Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus. Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine.

4.6 Pregnancy and lactation

In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of the ductus arteriosus), use in the last trimester is contraindicated. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child.

NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.