

# DIFSOM

## (Diclofenac Sodium)

### Composition:

Each enteric coated tablet contains:  
Diclofenac Sodium.....50mg.  
BP Specifications.

### Description:

Diclofenac sodium is a phenyl acetic acid derivative which has analgesic, antipyretic and anti-inflammatory action. It is rapidly absorbed into plasma with peak levels occurring at around two hours. It is extensively bound to proteins. The plasma half-life is in order of 1.2 to 1.8 hours. Diclofenac sodium penetrates rapidly into synovial fluid of patients with active rheumatoid arthritis and chronic joint effusions.

### Indications:

Diclofenac sodium is indicated for the treatment of pain and inflammation in rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, chronic juvenile arthritis and in other musculo-skeletal disorders including peri-arthritis, bursitis, tendonitis, tenosynovitis, strains and dislocations. Also controls pains and inflammation in acute gout and minor surgery.

### Side Effects:

Gastro-intestinal disturbances, headache, tinnitus, dizziness, skin rashes, fluid retention and peripheral oedema. Very rarely peptic ulcer, haematemesis or melaena, stools and blood dyscrasias.

### Precautions and Warnings:

As with other NSAIDs periodic monitoring of liver enzymes, creatinine, blood count and urine analysis should be carried out. Avoid in patients with history of peptic ulcer, haematemesis or melaena, bleeding diathesis or with severe hepatic or renal insufficiency. Rarely as with other NSAIDs anaphylaxis, laryngeal spasm and bronchospasm have been reported.

### Use in Pregnancy and Lactation:

Use in pregnancy should be avoided if possible because of the risk of premature closure of duct with prostaglandin inhibitors. Detected in breast milk, hence not recommended in nursing mothers.

### Drug Interactions:

Concomitant administration of diclofenac and aspirin is not recommended because diclofenac sodium is displaced from the binding sites and biliary excretion increased resulting in lower plasma concentration and AUC values for diclofenac sodium. Diclofenac sodium decreases lithium renal clearance and increases lithium plasma level, possibly leading to lithium toxicity. Concomitant treatment with potassium-sparing diuretics has resulted in increased serum potassium levels. Diclofenac sodium reduces both the diuretic and natriuretic effect of chlorthalidone. The antihypertensive effect of hydrochlorothiazide is attenuated by diclofenac sodium.

### Interactions:

- Methotrexate
- Lithium
- Digoxin
- Diuretics
- Cyclosporin
- Anticoagulants
- Oral hypoglycemic agents
- Steroids

### Dosage and Administration:

Usual dose is one tablet 2 to 3 times daily (100-150mg). For children above 8 years of age, the dose is 1 to 3mg/kg/day in divided doses or as directed by the physician. Not recommended for children under 8 years of age.

### Presentation:

Difsom is available as:  
Round biconvex enteric coated tablets 50 mg: (2x10) blister Pack.

### Storage:

Protect from heat, sunlight and moisture.  
Store below 30°C.  
Keep out of the reach of children.

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ دوا کو دھوپ، گرمی اور نمی سے بچائیں۔  
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔



Manufactured By:

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