Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Potent CYP2C9 inhibitors: Caution is recommended when co-prescribing diclofenac with potent CYP2C9 inhibitors (such as voriconazole), which could result in a significant increase in peak plasma concentrations and exposure to diclofenac due to inhibition of diclofenac metabolism.

How Supplied :
Box of 100 tablets (10 strips of 10 tablets each)

Storage :
Store protected from light & moisture
at a temperature not exceeding 30°C.

® : Registered Trade Mark in India

MM REG NO. R2508A4106

Manufactured by :
WIN-MEDICARE PVT. LTD.
Modipuram-250 110, U.P., India.

UMESH MODI GROUP MODINAGAR

Marketed by :
Win-Medicare
WIN-MEDICARE PVT. LTD.
Office :
1400, Modi Tower, 98, Nehru Place,
New Delhi - 110 019, India.

PMPA043 Ed.VII / 05.21

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rx

SOLUDOL®

Diclofenac Dispersible Tablets

Description :
Each dispersible tablet contains :
46.5 mg of Diclofenac Free Acid equivalent to
Diclofenac Sodium BP 50 mg
Colour : Tartrazine

Soludol® Dispersible Tablets have a rapid onset of action, as they are in a pharmaceutical formulation which renders them very useful for the short term treatment of painful, inflammatory conditions. Besides, being soluble and drinkable, they are of special help in patients who have difficulty in swallowing conventional tablets.

Mode of Action :
Soludol® Dispersible Tablets contain diclofenac free acid, a non-steroidal, anti-inflammatory drug (NSAID). In pharmacological studies, diclofenac has shown anti-inflammatory, analgesic and antipyretic activity. As with other NSAIDs, its mode of action is not known; its ability to inhibit prostaglandin synthesis, however, may be involved in its anti-inflammatory activity, as well as contribute to its efficacy in relieving pain related to inflammation. With regard to its analgesic effect, diclofenac is not a narcotic.

In rheumatic disease, the anti-inflammatory and analgesic properties of Soludol® elicit a clinical response characterised by marked relief from signs and symptoms such as pain at rest or on movement, morning stiffness and swelling of the joints, as well as by an improvement in joint function.

Pharmacokinetics :
Diclofenac is well absorbed after oral administration and peak plasma levels are usually attained in 2-3 hours. Absorption occurs more rapidly when ingested on an empty stomach than when administered during or after a meal. Plasma concentrations show a linear relationship to the size of the dose administered. However, concentrations are maintained at higher levels in the synovial fluid than in plasma.

A large proportion of diclofenac is metabolised in the liver and about 30% of the ingested dose undergoes first pass metabolism. Approximately 65% of the dose is exereted in the urine, and approximately 35% in the bile.

Plasma concentration of diclofenac declines from peak levels in a biexponential fashion, with the terminal phase having a half-life of approximately 2 hrs. However, the elimination half-life from the synovial fluid is about three times longer than that from plasma.

Pharmacokinetic behaviour remains unchanged following repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

No relevant age-dependent differences in the drug's absorption, metabolism, or excretion have been observed.

More than 99% is protein bound.

Indications :
Soludol® is indicated for pain & inflammation in musculoskeletal disorders such like acute gout, rheumatic diseases including juvenile idiopathic arthritis, post-operative and post-traumatic pain, flare up of joint pain, myalgia, sprains and strains, painful dental conditions, primary dysmenorrhoea, headache, tonsilitis, etc.

Contraindications :
Contra-indicated in patients with a history of hypersensitivity to aspirin or any other NSAID - Which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID.
With systemic use : Active gastro-intestinal bleeding, active

gastro-intestinal ulceration, avoid suppositories in proctitis, cerebrovascular disease, history of gastrointestinal bleeding related to previous NSAID therapy, history of gastro-intestinal perforation related to previous NSAID therapy, history of recurrent gastro-intestinal haemorrhage (two or more distinct episodes), history of recurrent gastro-intestinal ulceration (two or more distinct episodes), ischaemic heart disease, mild to severe heart failure, peripheral arterial disease.
Third trimester of pregnancy (risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the new born)

Precautions :

- Close medical surveillance is required in patients with symptoms indicative of gastro-intestinal disease, a history of dyspepsia, Crohn's disease, ulcerative colitis, etc., and in patients with blood coagulation disorders, connective tissue disorders and those with severe cardiac, hepatic or renal disease.
- Caution should be exercised in elderly patients, who are generally more likely to experience side effects.
- In patients receiving long-term treatment, it is advisable to check blood counts at intervals and monitor hepatic and renal function.
- When given along with oral anticoagulants or oral antidiabetics, as a precaution the dosage of these drugs should be carefully adjusted in accordance with prothrombin time and blood glucose levels respectively.

Pregnancy & Lactation :

With systemic use Avoid unless the potential benefit outweighs the risk. Avoid during the third trimester (risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn); onset of labour may be delayed and duration may be increased.
With systemic use Use with caution during breast-feeding. Amount in milk too small to be harmful.

Side Effects :

At recommended doses, Soludol® is generally well tolerated. However, with diclofenac, the following side effects have been reported

Rare

- Alveolitis, aseptic meningitis (patients with connective-tissue disorders such as systemic lupus erythematosus may be especially susceptible), hepatic damage, interstitial fibrosis associated with NSAIDs can lead to renal failure, pancreatitis, papillary necrosis associated with NSAIDs can lead to renal failure, pulmonary eosinophilia, Stevens-Johnson syndrome, toxic epidermal necrolysis, visual disturbances

Frequency not known

- With systemic use Angioedema, blood disorders, bronchospasm, colitis (induction of or exacerbation of), Crohn's disease (induction of or exacerbation of), depression, diarrhoea, dizziness, drowsiness, fluid retention (rarely precipitating congestive heart failure), gastro-intestinal bleeding, gastro-intestinal discomfort, gastro-intestinal disturbances, gastro-intestinal ulceration, haematuria, headache, hearing disturbances, hypersensitivity reactions, insomnia, nausea, nervousness, photosensitivity, raised blood pressure, rashes, renal failure (especially in patients with pre-existing renal impairment), tinnitus, vertigo.

Dosage and Administration :

As a rule, the daily dose for adults is 1 tablet, 2 or 3 times a day. The drug should be taken with or after meals.

Soludol® tablet should preferably be dispersed in a glass of water. Stir the water to fully disperse the tablet. Drink the solution, once the tablet has completely dispersed.

Soludol® should not be used in children below 14 years of age.

Drug Interactions :

The following interactions include those observed with diclofenac gastro-resistant tablets and/or other pharmaceutical forms of diclofenac.

Lithium: If used concomitantly, Soludol® may increase plasma concentrations of lithium Monitoring of the serum lithium level is recommended.

Digoxin: If used concomitantly, Soludol® may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended.

Diuretics and antihypertensive agents: Like other NSAIDs, concomitant use of Soludol® with diuretics and antihypertensive agents (e.g. beta-blockers, angiotensin converting enzyme (ACE) inhibitors may cause a decrease in their antihypertensive effect via inhibition of vasodilatory prostaglandin synthesis. Therefore, the combination should be administered with caution and patients, especially the elderly, should have their blood pressure periodically monitored. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy periodically thereafter, particularly for diuretics and ACE inhibitors due to the increased risk of nephrotoxicity.

Drugs known to cause hyperkalemia: Concomitant treatment with potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim may be associated with increased serum potassium levels, which should therefore be monitored frequently.

Anticoagulants and anti-platelet agents: Caution is recommended since concomitant administration could increase the risk of bleeding. Although clinical investigations do not appear to indicate that diclofenac has an influence on the effect of anticoagulants, there are reports of an increased risk of haemorrhage in patients receiving diclofenac and anticoagulant concomitantly. Therefore, to be certain that no change in anticoagulant dosage is required, close monitoring of such patients is required. As with other nonsteroidal anti-inflammatory agents, diclofenac in a high dose can reversibly inhibit platelet aggregation.

Other NSAIDs including cyclooxygenase-2 selective inhibitors and corticosteroids: Coadministration of diclofenac with other systemic NSAIDs or corticosteroids may increase the risk of gastrointestinal bleeding or ulceration. Avoid concomitant use of two or more NSAIDs.

Selective serotonin reuptake inhibitors (SSRIs): Concomitant administration of SSRI's may increase the risk of gastrointestinal bleeding.

Antidiabetics: Clinical studies have shown that Soludol® can be given together with oral antidiabetic agents without influencing their clinical effect. However there have been isolated reports of hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of the antidiabetic agents during treatment with diclofenac. For this reason, monitoring of the blood glucose level is recommended as a precautionary measure during concomitant therapy.

Methotrexate: Diclofenac can inhibit the tubular renal clearance of methotrexate hereby increasing methotrexate levels. Caution is recommended when NSAIDs, including diclofenac, are administered less than 24 hours before treatment with methotrexate, since blood concentrations of methotrexate may rise and the toxicity of this substance be increase. Cases of serious toxicity have been reported when methotrexate and NSAIDs including diclofenac are given within 24 hours of each other. This interaction is mediated through accumulation of methotrexate resulting from impairment of renal excretion in the presence of the NSAID.

Ciclosporin: Diclofenac, like other NSAIDs, may increase the nephrotoxicity of ciclosporin due to the effect on renal prostaglandins. Therefore, it should be given at doses lower than those that would be used in patients not receiving ciclosporin.

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus. This might be mediated through renal antiprostagladin effects of both NSAID and calcineurin inhibitor.

Quinolone antibacterials: Convulsions may occur due to an interaction between quinolones and NSAIDs. This may occur in patients with or without a previous history of epilepsy or convulsions. Therefore, caution should be exercised when considering the use of a quinolone in patients who are already receiving an NSAID.

Phenytoin: When using phenytoin concomitantly with diclofenac, monitoring of phenytoin plasma concentrations is recommended due to an expected increase in exposure to phenytoin.

Colestipol and cholestyramine: These agents can induce a delay or decrease in absorption of diclofenac. Therefore, it is recommended to administer diclofenac at least one hour before or 4 to 6 hours after administration of colestipol/ cholestyramine.

Cardiac glycosides: Concomitant use of cardiac glycosides and NSAIDs in patients may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.