PACK INSERT

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

Rx

Diclomol® SR

Sustained Release Tablets of Diclofenac Sodium

Anti-Inflammatory and Analgesic

Description :
Each sustained-release film-coated tablet contains :
Diclofenac Sodium BP: 100 mg
Colour : Red Oxide of Iron and Titanium Dioxide.

Mode of action :
Diclomol® SR tablets for oral administration contain a non-steroidal compound with pronounced anti-inflammatory, analgesic and antipyretic properties.

Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is regarded as having an important bearing on its mechanism of action. Prostaglandins play a major role in the causation of inflammation, pain and fever.

In rheumatic diseases, the anti-inflammatory and analgesic properties of Diclomol® SR elicit a clinical response characterised by marked relief from signs and symptoms such as pain at rest, pain on movement, morning stiffness, and swelling of the joints, as well as by an improvement in function. Diclomol® SR is particularly suitable for patients in whom a daily dosage of 100 mg is appropriate to the clinical picture. The possibility of prescribing the drug in a single dose considerably simplifies long-term treatment and helps to avoid the possibility of dosage errors. For milder cases, where a lower dosage is sufficient, other forms of Diclomol® are available.

Pharmacokinetics :
Diclofenac is completely absorbed from the sustained-release tablets. As a result of delayed release of the active substance, the peak plasma concentrations attained are lower than those achieved following the administration of conventional dosage forms. On the other hand, concentrations remain measurable for some hours after attaining their peak. Absorption sets in later following ingestion of a sustained-release tablet either with or after a meal than it does following administration on an empty stomach. The mean peak plasma concentration of 0.43 µg/ml (1.35 µmol/litre) is attained on average about 5 hours after ingestion of a sustained-release tablet of 100 mg.

Since about half the active substance is metabolised during its first passage through the liver ("first pass" effect), the area under the concentration curve (AUC) is about half as large following oral administration as it is, following a parenteral dose of equal size. Diclofenac becomes bound to serum proteins at a rate of 99.7%, chiefly to albumin.

The total systemic clearance of diclofenac in plasma is 263 ± 56 ml./min (mean value ± SD). The terminal half-life in plasma is 1-2 hours.

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

Diclofenac enters the synovial fluid, where maximum concentrations are measured 2-4 hours after peak plasma values have been attained. The apparent half-life for