

## Clofec Tablet Clofec Injection



### Composition:

Clofec tablet is an enteric coated, biconvex compressed yellow tablet. Each tablet contains 25 mg diclofenac sodium which is known chemically as sodium (2-(2,6 dichloroanilino)phenyl)-acetate. Clofec Injection is a colorless solution. Each 3 ml contains 75 mg diclofenac sodium.

### Therapeutic Properties:

Diclofenac sodium has analgesic, antipyretic and anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase (Cyclo-oxygenase). It is used for the relief of pain and inflammation in conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout. Diclofenac is absorbed from the gastro-intestinal tract but is subject to first pass metabolism. Peak plasma concentrations occur about 1 to 4 hours after ingestion of enteric coated tablets. At therapeutic concentrations, it is more than 99% bound to plasma proteins. The terminal plasma half life is about 1 to 2 hours. Diclofenac is excreted primarily in the form of metabolites, mainly in the urine but also in the bile.

### Indications:

It is indicated for the relief of pain and inflammation in conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout, myositis and bursitis.

### Adverse/Side Effects:

The most common adverse effects include gastro-intestinal disturbances such as peptic ulceration and gastro-intestinal bleeding, headache, dizziness, nervousness, skin rashes, pruritus, tinnitus, abnormality of liver function tests, impairment of renal function including intestinal.

### Contraindications:

Caution is needed in patients who have peptic ulcer, renal impairment, hepatic dysfunction.

### Drug Interactions:

Diclofenac may cause increased concentrations of digoxin and lithium.

### Incompatibilities:

None has been reported.

### Usage During Pregnancy:

Diclofenac sodium is not recommended for use in the first trimester of pregnancy.

Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation.

### Dosage:

Tablet: Adult initial dose is 1 to 2 tablets three times a day after meal maintenance dose is 1 tablet three times a day after meal.

Injection: The adult dosage is generally 75 mg daily, injected deep intragluteally into the upper outer quadrant. In severe cases, two injections can be given per day, one into each gluteal muscle.

### Storage Conditions:

Store in cool dry place. Protect from light. Keep out of reach of children.

### Packing:

In bottle of 500,1000 tablets.

In box of 50x3 ml ampoules.

Mfd. by **Atlantic Laboratories Corporation Ltd.** Bangkok, Thailand.  
Distributed by **VANA Corp.,Ltd.** Bangkok, Thailand.

170222 (R/SIN)

จาก SIZE : 10x 20 cm. เก่า  
เปลี่ยนเป็น 10x21.3 cm. ใหม่