DENTAIN TABLETS

DESCRIPTION

Dentain Tablet contains diclofenac potassium, which is a benzene acetic acid derivative. The chemical name of diclofenac potassium is 2-[(2,6-dichlorophenyl)amino] benzene acetic acid, monopotassium salt. Its molecular formula is $C_{14}H_{10}Cl_2NKO_2$.

Dentain Tablet also contains Paracetamol, which is a non-opiate, non-salicylate analgesic and antipyretic agent. The molecular formula is $C_8H_9NO_2$

COMPOSITION

Each film-coated tablet contains:

Diclofenac Potassium	50 mg
Paracetamol	500 mg

PHARMACOLOGY

Diclofenac is a non-steroidal anti-inflammatory drug [NSAID] that exhibits anti-inflammatory, analgesic, and antipyretic activities. NSAIDs relieve pain and inflammation by inhibiting cyclooxygenase enzyme and ultimately the synthesis of prostaglandins. Prostaglandins have an important role to play in the production of inflammation, pain and fever in the body.

Diclofenac is available as the sodium or potassium salt. The former is enteric-coated to ensure optimum bioavailability but this leads to some delay in the onset of action, though in chronic therapy this is not significant. The potassium salt is absorbed rapidly and action sets in much earlier.

Paracetamol is an analgesic and antipyretic agent. When used together, Paracetamol potentiates the action of Diclofenac potassium in providing early pain relief.

INDICATIONS

- ✓ Dental pain of varied etiology
- ✓ Orofacial / craniofacial pain
- ✓ Post-extraction pain
- ✓ Temporomandibular joint disorder

DOSAGE

Adults: 1 Tablet 2-3 times daily.

CONTRAINDICATIONS

- ❖ Hypersensitivity
- ❖ Active peptic ulcer or GI bleeding
- ❖ History of allergic responses to aspirin or other NSAID
- ❖ Acute porphyria

SPECIAL PRECAUTIONS

Clinical trials of several COX-2 selective and nonselective NSAIDs given for up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, the lowest effective dose should be used for the shortest duration possible.

NSAIDs can lead to onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Blood pressure (BP) should be monitored closely during the course of therapy.

Fluid retention and edema have been observed in some patients taking NSAIDs. Dentain Tablets should be used with caution in patients with fluid retention or heart failure.

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.

DRUG INTERACTIONS

Aspirin: Concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects.
Methotrexate: NSAIDs have been reported to competitively inhibit methotrexate accumulation and could enhance the toxicity.
Cyclosporine: NSAIDs, may affect renal prostaglandins and increase the toxicity of certain drugs like cyclosporine.
ACE Inhibitors: Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE inhibitors.
Furosemide: Studies have shown that Diclofenac can reduce the natriuretic effect of furosemide and thiazides in some patients as a result of inhibition of renal prostaglandin synthesis.
Warfarin: The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that users of both drugs together have a risk of serious GI bleeding.

PREGNANCY

There are no adequate and well-controlled studies in pregnant women. However because of the known effects of NSAIDs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy (particularly late pregnancy) should be avoided.

NURSING MOTHERS

It is not known whether Diclofenac Potassium is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue Dentain, taking into account the importance of the drug to the mother.

PEDIATRIC USE

Safety and effectiveness of Dentain in pediatric patients have not been established

ADVERSE REACTIONS

The most common adverse effects are: nausea, heartburn, diarrhoea, headache, dizziness, salt and fluid retention, high blood pressure, oedema feet, constipation, flatulence, loss of appetite and abdominal pain.

PRESENTATION

Blister pack of 10 Tablets.