

DENTAIN PLUS TABLETS

DESCRIPTION

Dentain Plus Tablet is a fixed dose combination containing Serratiopeptidase, Diclofenac potassium and Paracetamol.

Serratiopeptidase is a proteolytic enzyme. Diclofenac potassium 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 Plus 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:

Serratiopeptidase	10 mg
Diclofenac Potassium	50 mg
Paracetamol I.P.	500mg

PHARMACOLOGY

Serratiopeptidase is a proteolytic enzyme derived from bacteria belonging to genus Serratia. It has been available for clinical use for more than a decade. The purified enzyme is absorbed well from the intestines. It binds to alpha-2-macroglobulin in the blood in the ratio of 1:1, which helps to mask its antigenicity but retains its enzymatic activity. It is slowly, transferred to the site of inflammation. Serratiopeptidase hydrolyses bradykinin, histamine and serotonin responsible for oedema. It reduces swelling, improves microcirculation, liquefies pus and sputum and enhances the action of antibiotics.

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 has a fast onset of action, just 20 minutes.

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

INDICATIONS

- ✓ Pericoronitis
- ✓ Pulpitis
- ✓ Gingivitis
- ✓ Molar Impaction
- ✓ Dental abscess
- ✓ Post operative edema
- ✓ Co-prescription with antibiotics in infections e.g. Alveolar abscess,

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, 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 Plus 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 in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate.

Cyclosporine: Diclofenac Potassium, like other 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: Clinical studies, as well as post-marketing observations, have shown that Diclofenac Potassium can reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to 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 higher than users of either drug alone.

With anticoagulative agents, Serratiopeptidase may increase anticoagulative effect and therefore **Dentain Plus Tablets** must not be used in such patients.

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 Plus, taking into account the importance of the drug to the mother.

PEDIATRIC USE

Safety and effectiveness of Dentain Plus 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.

Serratiopeptidase - Hypersensitivity reactions, such as rash or redness, may infrequently occur. If such reactions occur, **Dentain Plus Tablets** should be discontinued.

PRESENTATION

Blister pack of 10 Tablets.