

DEPI-SP[®]

(Diclofenac Potassium, Paracetamol & Serratiopeptidase Tablets)

Composition:

Each film coated tablet Contains:

Diclofenac Potassium BP	50 mg
Paracetamol IP.....	325 mg
Serratiopeptidase IP... ..	10 mg
Excipients	q.s.

Clinical Pharmacology:

Diclofenac potassium is a NSAID (non-steroidal anti-inflammatory drug) that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of diclofenac potassium, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. Paracetamol has analgesic and antipyretic actions. Serratiopeptidase is also a potent anti-inflammatory agent that exerts fibrinolytic and anti-oedematic actions. The therapeutic enzyme reduces inflammation and swelling in the affected area.

Indications:

- Quick relief from pain for the longer duration
- Also for Inflammatory swelling & oedema

Use in special population:

Elderly:

Caution is indicated in the elderly on basic medical grounds. The elderly have increased frequency of adverse reactions to NSAIDs especially gastro intestinal bleeding and perforation which may be fatal. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight.

Paediatric Patients:

Not recommended for children under 10 years of age.

Contraindications:

- Hypersensitivity to any of the constituents in DEPI-SP.
- Patients with active peptic ulcer/haemorrhage or perforation or who have active GI bleeding or other active bleedings, e.g. cerebrovascular bleedings.
- Patients with severe renal and hepatic failure.
- Established congestive heart failure (NYHAI–IV), ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

Precautions and Warnings:

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. The use of Diclofenac potassium with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects.

Hypersensitivity reactions:

As with other non-steroidal anti-inflammatory drugs, allergic reactions, including anaphylactic/anaphylactoid reactions, can occur without earlier exposure to the drug.

Infection:

Like other NSAIDs, Diclofenac Potassium tablets may mask the signs and symptoms of infection due to their pharmacodynamic properties.

Cardiovascular, Renal and Hepatic Impairment:

The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure.

Drug Interactions:

Other NSAIDs including cyclooxygenase-2 selective inhibitors and corticosteroids: Co-administration 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.

Diuretics and antihypertensive agents:

Like other NSAIDs, concomitant use of diclofenac 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.

Digoxin:

If used concomitantly, diclofenac may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended.

Adverse effects:

Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, Palpitations, chest pain.

Overdosage:

There is no typical clinical picture resulting from diclofenac over dosage. Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, dizziness, disorientation, excitation, coma, drowsiness, tinnitus, fainting, occasionally convulsions. In rare cases of significant poisoning acute renal failure and liver damage are possible.

Route of administration: Oral.

Type of tablet: Film coated tablet.

Dosage:

As Directed by the Physician.

Storage

Store in cool, dry & dark place.

SCHEDULE H PRESCRIPTION DRUG CAUTION- Not to be sold by retail without the Prescription of a Registered Medical Practitioner.

Presentation: Depi-SP tablet available as 10 x10 tablet

Marketed By:



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