Composition:
**Diclonac Plus Injection:** Each 2 ml sterile solution contains Diclofenac sodium BP 75 mg and Lidocaine Hydrochloride BP 20 mg.

Pharmacology:
**Diclonac Plus** contains Diclofenac sodium, which is a potent non-steroidal anti-inflammatory drug (NSAID) with marked analgesic and anti-inflammatory properties. The actions of Diclofenac appear to be associated principally with the inhibition of prostaglandin synthesis by inhibiting cyclo-oxygenase the enzyme that catalyzes the formation of prostaglandin precursor (endoperoxides) from arachidonic acid. Peak plasma concentration occurs within half an hour. Diclofenac is 99.7% bound to plasma proteins and plasma half-life for the terminal elimination phase is 1-2 hours. About 60% of the administered dose is excreted via the kidney in the form of metabolites and less than 1% in unchanged form. The remainder is excreted via the bile in metabolised form.

Indications and Uses:
It is indicated mainly for the relief of pain and inflammation in various conditions: musculoskeletal and joint disorders such as bursitis and tendonitis; soft tissue disorder such as sprains and strains; and other painful conditions such as renal colic, acute gout, dysmenorrhoea, migraine and following surgical procedures. It has also been used in the management of active keratoses and fever.

Dosage and Administration:
It may be given by deep intramuscular injection into gluteal muscle in a dose of 75 mg once daily or if required in severe conditions. To prevent post-operative pain 25 to 50 mg diclofenac sodium may be given after surgery over 15 to 60 minutes followed by 5 mg per hour to a maximum of 150 mg daily. It is also used intramuscularly in renal colic in a dose of 75 mg repeated once after 30 minutes if necessary.

Contraindications:
Moderate or severe renal impairment, Hypovolaemia or dehydration, In patients with history of haemorrhagic diseases, cerebrovascular bleeding or asthma, patients undergoing surgery with a high risk of haemorrhage.

Use in Pregnancy and Lactation:
Should not be used in pregnancy unless there are compelling reasons for doing so. The lowest effective dosage should be used. This type of drugs is not recommended during the last trimester of pregnancy. Very small quantities of Diclofenac sodium may be detected in breast milk, but no undesirable effects on the infant are to be expected.

Side-effects:
Gastrointestinal side effects: Gastrointestinal discomfort, nausea and diarrhea
CNS related: Headache, vertigo, dizziness, nervousness, tinnitus, depression, drowsiness and insomnia.
Hypersensitivity reactions: Fever, angioedema, bronchospasm and rashes.
Haematological effects: Anemia, thrombocytopenia, neutropenia, eosinophilia and agranulocytopenia.

There may be pain and occasionally tissue damage at the site of injection when Diclofenac sodium is given intramuscularly.

Precautions and Warning:
Should not be given to the patients with peptic ulceration and should be used with caution, if at all in patients of gastrointestinal effects; it may be taken with or after food or milk. It should be used with caution in patients with infections, sign symptoms such as fever and inflammation may be masked and also used with caution in patients with asthma or allergic disorder. Other general precautions to be observed include administration to patients with haemorrhagic disorders, hypertension and impaired renal function, hepatic or cardiac function. Patients undergoing therapy with Diclofenac sodium and Lidocaine hydrochloride therapy may be needed to be monitored for the development of blood, kidney, liver or eye disorders.

Drug Interactions:
Exhibit interactions with oral anticoagulants, lithium, methotrexate and cardiac glycosides, ACE inhibitors and potassium sparing diuretics.

Packaging:
**Diclonac Plus Injection:** Each box contains 2X5's ampoules in blister pack.

Manufactured by
Ziska Pharmaceuticals Ltd.
Gazipur, Bangladesh