GEBEDOL **GB PHARMA LIMITED**
DICLOFENAC SODIUM AND PARACETAMOL TABLETS

1. Name of the medicinal product

GEBEDOL

(DICLOFENAC SODIUM AND PARACETAMOL TABLETS)

2. Qualitative and quantitative composition

Each uncoated tablets contains

Diclofenac sodium BP ……..50mg
Paracetamol BP ……..500mg
Excipients ……...…...Q.S.

3. Pharmaceutical form

Uncoated tablets

White to off white color, round shape, uncoated tablets breakline on one side and plain on other side **.**

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GEBEDOL is indicated for the treatment of following.

- Acute painful arthritic conditions.
- Pelvic inflammatory conditions like pelvic cellulites, pelvic peritonitis, pelvic abscess.
- Dental Inflammatory conditions.
- Post operative pain and inflammation.
- Short term maintenance therapy of articular rheumatic.
- Fast & effective relief from pain & inflammation.

4.2 Posology and method of administration

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

For oral administration

Adults:

75-150mg daily in two or three divided doses.

The recommended maximum daily dose is 150mg.

Special populations

Elderly

Although the pharmacokinetics of GEBEDOL are not impaired to any clinically relevant extent in elderly patients, nonsteroidal anti-inflammatory drugs should be used with particular caution in such patients who generally are more prone to adverse reactions. In particular it is

recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight and the patient should be monitored for GI bleeding during NSAID therapy.

Renal impairment

Diclofenac is contraindicated in patients with severe renal impairment. No specific studies have been carried out in patients with renal impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering diclofenac to patients with mild to moderate renal impairment.

Hepatic impairment

Diclofenac is contraindicated in patients with severe hepatic impairment. No specific studies have been carried out in patients with hepatic impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering diclofenac to patients with mild to moderate hepatic impairment.

Paediatric population

Not recommended

Method of administration

Oral administration.

4.3 Contraindications

GEBEDOL is contraindicated in patients with peptic ulcer, gastrointestinal bleeding and history of aspirin-induced asthma. GEBEDOL is contraindicated in patient having hypersensitivity to any ingredients of formulation.

4.4 Special warnings and precautions for use

GEBEDOL should be used with caution in patients with a history of dyspepsia or peptic ulcer, hematemesis, blood coagulation disorders, asthma and severe hepatic or renal disease. Occasional blood counts may be carried out in patients undergoing prolonged treatment. GEBEDOL should be used in women of Childbearing potential only when, in the judgment of the Physician, the potential benefits outweigh the possible risks. GEBEDOL should be discontinued if liver dysfunction occurs.

4.5 Interaction with other medicinal products and other forms of interaction

Aspirin : Concomitant administration can result in lower plasma concentrations, peak plasma levels, and AUC values.

Digoxin, Methotrexate, Cyclosporin: Diclofenac Sodium may affect renal Prostaglandins and increase the toxicity of certain drugs. Ingestion of Diclofenac Sodium may increase serum concentrations of digoxin and methotrexate and increase cyclosporine nephrotoxicity.

Lithium : Diclofenac Sodium decreases lithium renal learance and increases lithium plasma levels. lithium toxicity may can also develop.

Oral Hypoglycemics: Diclofenac Sodium may alter a diabetic patient' response to insulin or oral hypoglycemic agents.

Diuretics : Diclofenac Sodium can inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels.

Cholestyramine : Reduces absorption of Acetaminophen.

Activated charcoal : Administered immediately reduces absorption of Acetaminophen.

Domperidone & metoclopramide : Enhance absorption of Acetaminophen.

Alcohol: Chronic excessive ingestion of alcohol potentiates hepatotoxicity of Acetaminophen

Zidovudine: Effects of zidovudine may be decreased.

CNS Depressants: Central nervous system depressants with Chlorzoxazone may have an additive effect.

GEBEDOL when administered concomitanlly with alcohol or any other CNS depressants, an additive effect is observed

4.6 Pregnancy and lactation

Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take GEBEDOL tablets during the last 3 months of pregnancy as it may affect the baby's circulation.You should advise your doctor or pharmacist if you think you might be pregnant or are up to 6 months pregnant.

Taking GEBEDOL tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

You should avoid taking GEBEDOL tablet whilst breast feeding.

4.7 Effects on ability to drive and use machines

Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking diclofenac, should refrain from driving or using machines. Paracetamol has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Gastrointestinal effects rarely encountered with GEBEDOL are dyspepsia, gastritis, peptic ulceration, gastrointestinal bleeding and retention of sodium and water. Blood dyscrasias may be encountered during long term administration. GEBEDOL may shown following adverse effects like gastric irritation, dyspepsia, gastritis, peptic ulceration, gastro-intestinal bleeding. nausea, lethargy, headache.

4.9 Overdose

GEBEDOL may cause nausea, vomiting, pain abdomen, dizziness, somnolence, headache, sweating, pancreatitis, hepatic failure and acute renal failure.Treatment, if required, includes gastric lavage, activated charcoal and other symptomatic measures as per medical advice.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non Steroidal Ant-inflammatory And Anti-Rheumatic.

ATC Code: Paracetamol: N02BE01, Diclofenac sodium: M01AB05

Diclofenac Sodium has potent anti-inflammatory, analgesic and antipyretic actions. The mechanism of actions is inhibition of the enzyme, cyclo-oxygenase in the pathway of prostaglandin (PG) synthesis. PGs are known to be associated with inflammation. Its ability to inhibit prostaglandin synthesis (cyclo-oxygenase) is involved in its anti-inflammatory activity, as well as contributes to its efficacy in relieving pain related to inflammation and primary dysmenorrheal. With regard to its analgesic effect, Diclofenac Sodium is not a narcotic analgesic.

Paracetamol has analgesic and anti-pyretic properties due to its ability to inhibit prostaglandin synthesis in the central nervous system (CNS). Acetaminophen produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulating center.

5.2 Pharmacokinetic properties

Diclofenac Sodium is rapidly absorbed from the gut and is subject to first-pass metabolism. The active substance is 99.7% protein bound and plasma half-life for the terminal elimination phase is 1-2 hours. Administered dose is excreted via the kidneys and via the bile in the form of metabolites. Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber that are additional to those included in other sections.

6. Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Ingredients	Grade
1	Starch	BP
2	Di basic calcium phosphate	BP
3	Sodium lauryl sulphate	BP
4	PVPK-30	BP
5	Magnesium stearate	BP
6	Sodium starch glycolate	BP
7	Talcum	BP
8	Colloidal silicon dioxide	BP
9	Polacriline potassium (kyron t-314)	BP

6.2 Incompatibilities

None stated

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30℃. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and contents of container

Primary Packing: 1 x 10 Tablets are packed in one Alu- PVC blister.

Secondary Packing: Such 01 blisters are packed in a printed carton along with package insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

GBGL Pharma Limited