GEBEDOL FORTE **GB PHARMA LIMITED**
DICLOFENAC SODIUM, ACETAMINOPHEN AND CHLORZOXAZONE TABLETS

1. Name of the medicinal product

GEBEDOL FORTE

(DICLOFENAC SODIUM, ACETAMINOPHEN AND CHLORZOXAZONE TABLETS)

2. Qualitative and quantitative composition

Each uncoated tablets contains
Diclofenac sodium USP ……....50mg
Acetaminophen USP ……..…..500mg
Chlorzoxazone USP ……250mg
Excipients ……...…..…..Q.S.
Color : Erythrosine

3. Pharmaceutical form
Uncoated tablets

Light pink color oblong shape , uncoated tablet with break line on one side and plain on other side

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GEBEDOL Forte is indicated for the treatment of following.

- Skeletal muscle spasm associated with trauma (sprains, strains, fractures).
- 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

Adults : 1 tablet 2-3 times a day. Or As directed by the Physician.

Method of administration

Oral administration.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

GEBEDOL Forte 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 Forte should be used in women of Childbearing potential only when, in the judgment of the Physician, the potential benefits outweigh the possible risks. GEBEDOL Forte 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 Forte 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 Forte 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 Forte 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 Forte 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 Forte are dyspepsia, gastritis, peptic ulceration, gastrointestinal bleeding and retention of sodium and water. Blood dyscrasias may be encountered during long term administration. GEBEDOL Forte may shown following adverse effects like gastric irritation, dyspepsia, gastritis, peptic ulceration, gastro-intestinal bleeding. nausea, lethargy, headache.

4.9 Overdose

GEBEDOL Forte 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

ATC Code: Acetaminophen: N02BE01,

Diclofenac sodium: M01AB05

Chlorzoxazone: M03BB03

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.

Acetaminophen 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. Chlorzoxazone is a centrally-acting agent for painful musculoskeletal conditions. Chlorzoxazone acts primarily at the level of the spinal cord and subcortical areas of the brain where it inhibits multisynaptic reflex arcs involved in producing and maintaining skeletal muscle spasm of varied etiology. The clinical result is a reduction of the skeletal muscle spasm with relief of pain and increased mobility of the involved muscles.

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.

Acetaminophen 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 conjugate

Chlorzoxazone is rapidly metabolized and is excreted in the urine, primarily in a conjugated form as the glucuronide

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	Micro crystalline cellulose	BP
2	Starch	BP
3	P.V.P. K-30	BP
4	sodium methyl hydroxybenzoate	BP
5	Sodium propyl hydroxybenzoate	BP
6	Color erythrosine supra	IHS
7	Water	BP
8	purified talc	BP

9	Magnesium stearate	BP
10	Sodium starch glycolate	
11	Colloidal silicon dioxide (aerosil)	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