

Geskaprofen 25mg®

Film-coated Tablets

Company Name: Medizen Pharmaceutical Industries.

Generic Name: Dexketoprofen trometamol 36.9mg (equivalent to dexketoprofen 25mg.)

Pharmaceutical

Form: Film-coated tablets.

Composition:

Each tablet contains:

Active Ingredients:

Dexketoprofen trometamol 36.9mg (equivalent to dexketoprofen 25mg.)

Inactive Ingredients:

Lactose anhydrous, Purified Talc, Magnesium stearate, Croscarmellose, Carnauba wax, Titanium dioxide, PEG 8000, Red ferric oxide.

Pharmacological Action:

Geskaprofen® is a non-steroidal anti-inflammatory agent that possesses analgesic, anti-inflammatory and antipyretic activities. It is the active enantiomer of ketoprofen. Its mode of action, like that of other NSAIDs, is not completely understood but is related to the inhibition of the cyclooxygenase enzyme activity and prostaglandin synthesis.

Pharmacokinetics:

Dexketoprofen is the s-enantiomer of ketoprofen which has a more potent pharmacological action than ketoprofen. Dexketoprofen is readily absorbed from the gastrointestinal tract; peak plasma concentrations occur about 0.5 to 2 hours after a dose. When Dexketoprofen is given with food, the bioavailability is not altered but the rate of absorption is slowed. Dexketoprofen is 99% bound to plasma proteins and substantial concentrations of the drug is found in the synovial fluid. The elimination half-life in plasma is about 1.5 to 4 hours. Dexketoprofen is metabolized mainly by conjugation with glucuronic acid, and is mainly excreted in the urine.

Indications:

Geskaprofen® is an anti-inflammatory used in the treatment of mild to moderate pain such as musculoskeletal pain, dysmenorrhea or dental pain.

Dosage and Administration:

12.5 mg (1/2 tablet) every 4-6 hours or 25 mg (1 tablet) every 8 hours. The maximum dose is 75 mg (3 tablets) daily. In elderly, the maximum dosage is 50 mg (2 tablets) daily.

Contraindications:

Geskaprofen® is contraindicated in patients with a history of hypersensitivity to any other NSAID.

It is contra-indicated in severe heart failure and in patients with previous or active peptic ulceration or bleeding.

Side Effects:

Geskaprofen® rarely causes nausea and/or vomiting, abdominal pain, diarrhea, dyspepsia, insomnia, anxiety, headache, dizziness, somnolence, gastritis, constipation, dry mouth, flatulence and rash.

Drug Interactions:

Administration of dexketoprofen with the following drugs might lead to interactions:

- Other NSAIDs: The risk of gastrointestinal ulcers and bleeding may increase.
- Anti-coagulants, such as warfarin: The effects of warfarin may be enhanced.
- Heparins: Risk of hemorrhage.
- Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding.

- Lithium: Increases its blood levels which may reach toxic values.
- Methotrexate at high doses of 15 mg/week or more: May cause haematological toxicity.
- Hydantoines and sulphonamides: Increases the toxic effects of these substances.
- Diuretics, ACE inhibitors and angiotensin II receptor antagonists: May result in further deterioration of renal

functions.

- Pentoxifylline: Increases risk of bleeding.
- Sulfonylureas: NSAIDs can increase the hypoglycaemic effect of sulfonylureas.
- Beta-blockers: Diminishes its antihypertensive effects.
- Cyclosporin and tacrolimus: Enhances nephrotoxicity.

Pregnancy and Lactation:

It is advisable to avoid using **Geskaprofen®** during pregnancy unless the potential benefit outweighs

the risk.

Precautions and Warnings:

- Safety of usage in children has not been established.
- Usage with concomitant other NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.
- Gastrointestinal bleeding, ulceration or perforation have been reported with all NSAIDs at anytime during treatment .When gastrointestinal bleeding or ulceration occur, the treatment should be withdrawn.
- Caution should be exercised in patients with impairment of hepatic and/or renal functions.
- Special caution should be exercised in patients with a history of cardiac disease.

Package:

Carton box containing 2 Pvc /aluminum strips; each strip has 10 film-coated tablets.

Storage:

- Keep at a temperature not exceeding 30°C in a dry place.
- Keep out of reach of children.

Instructions for Patients:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please refer to your doctor or pharmacist.
- Do not use more than one oral NSAID at a time.
- Combination with Aspirin can increase the risk of gastrointestinal side effects.
- It is recommended to be taken at least 30 minutes before meals.

Produced by Medizen Pharmaceutical Industries