VELFLEX

(Diclofenac Potassium)

50mg, 75mg & 100mg Tablets

ویل فلیکس

(ڈائی کلوفینیک پوٹاشیم)

۵۰ ملی گرام، ۷۵ ملی گرام اور ۱۰۰ ملی گرام گولیاں

COMPOSITION

Velflex 50mg Tablet
Each film coated tablet contains:
Diclofenac Potassium (USP)..... 50 mg
Product Complies USP Specs.

Velflex 75mg Tablet
Each film coated tablet contains:
Diclofenac Potassium (USP)..... 75 mg
Product Complies USP Specs.

Velflex 100mg Tablet
Each film coated tablet contains:
Diclofenac Potassium (USP)..... 100 mg
Product Complies USP Specs.

CLINICAL PARTICULARS

Therapeutic Indications
Short-term treatment in the following acute conditions:
- Post-traumatic pain, inflammation and swelling, e.g. due to sprains.
- Post-operative pain, inflammation and swelling, e.g, following dental or orthopaedic surgery.
- Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis.
- Painful syndromes of the vertebral column.,
- Non-articular rheumatism;
- As an adjuvant in severe painful inflammatory infections of the ear, nose, or throat, e.g., pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.

DOSAGE

Adults
The recommended initial daily dosage is '100-150 mg. In milder cases, as well as for children over 14 years of age, 50-100 mg daily or as directed by the physician. The dosage should generally be divided in 2-3 doses, In primary dysmenorrhoea the daily dosage should be individually adjusted and is generally 50-150 mg. Initially a dose of 50-100 mg should be given and, if necessary, raised in-the course of several menstrual cycles up to a maximum of 20mg/day. Treatment should be started upon appearance of the first symptoms and depending on the symptomatology, continued for few days. The tablets should be swallowed whole with liquid, preferably-before meals.

Contra-indications
Gastric or intestinal ulcer.
Known hypersensitivity to the active substance or the excipients. Like other non-steroidal anti-inflammatory drugs (NSAIDs), VELFLEX is also contra-indicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicyclic acid or other drugs with prostaglandin-synthetase inhibiting activity.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Warnings
Gastrointestinal bleeding or ulceration/perforation can occur at any time during treatment, with or without warning symptoms or a previous history. They generally have more serious consequences in the elderly. In the rare cases where gastrointestinal bleeding or ulceration occur in patients receiving VELFLEX, the drug should-be withdrawn. As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur in rare cases without earlier exposure to the drug. Like other NSAIDs, VELFLEX may mask the signs and symptoms of infection due to its pharmacodynamic properties.

Precautions
Close medical surveillance is imperative in patients with symptoms indicative of gastrointestinal disorders or a history suggestive of gastric or intestinal ulcer, patients with ulcerative colitis or Crohn's disease, and in patients suffering from impaired hepatic function.
As with other NSAIDs values of one or more liver-enzymes may increase. During prolonged treatment with VELFLEX monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash, etc.) VELFLEX should be discontinued. Hepatitis may occur without prodromal symptoms. Caution is called for when using VELFLEX in patients with hepatic porphyria, since VELFLEX may trigger an attack. Owing to the importance of prostaglandins in maintaining renal blood flow, particular caution is called for in patients with impaired cardiac or renal function, the elderly, patients being treated with diuretics
and patients with substantial extracellular volume depletion of any cause, e.g. before and after major surgery.
Monitoring of renal function is recommended as a precautionary measure when using VELFLEX in such cases. Discontinuation of therapy is normally followed by a return to the pretreatment state.
Treatment with VELFLEX in the aforementioned indications usually proves necessary only for a few days. But if, contrary to the recommendations for its use, VELFLEX is administered over a more prolonged period, it is advisable - as with other NSAIDs - to perform blood counts. Like other NSAIDS, VELFLEX may temporarily inhibit platelet aggregation. Patients with haemostatic disorders should be carefully monitored.Caution is indicated in the elderly on basic medical grounds. In particular it is recommended that the lowest effective dosage should be used in frail elderly patients or those with a low body weight.

Interactions
Lithium, digoxin: VELFLEX may raise plasma concentrations of lithium or digoxin.
Diuretics: Like other NSAIDS, VELFLEX may inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, which should therefore be monitored.
NSAIDs: Concomitant administration of systemic NSAIDs,. may increase the frequency of side effects.
Anticoagulants: Although clinical investigations do not appear to indicate that VELFLEX affects the action of anticoagulants, there are isolated reports of an increased risk of haemorrhage in patients receiving VELFLEX and anticoagulants concomitantly. Close monitoring of such patients is therefore recommended.
Antidiabetics: Clinical studies have shown that VELFLEX can be given together with oral antidiabetic agents without influencing their clinical effect. However, isolated cases have been reported of both hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of hypoglycaemic agents during treatment with VELFLEX.
Methotrexate: Caution is called for if NSAIDs are administered less than 24 hours before or after treatment with methotrexate. since blood concentrations of methotrexate may rise and the toxicity of this substance be increased.
Cyclosporin: The effects of NSAIDs on renal prostaglandins may increase the nephrotoxicity of cyclosporin.
Quinolone antibacterials: There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

PREGNANCY AND LACTATION

Pregnancy
During pregnancy VELFLEX should be employed only compelling reasons and only in the lowest effective doses. As in the case of other prostaglandin-synthetase inhibitors, this applies particularly to the last 3 months of pregnancy, (owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus).

Lactation
Following oral doses of 50 mg administered every 8 hours, the active substance passes into the breast milk, but in quantities so small that no undesirable effects on the infant are to be expected.

UNDESIRABLE EFFECTS

Gastrointestinal Tract
Occasional: epigastric pain, other gastrointestinal disorders such as nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia.
Rare: gastrointestinal bleeding (haematemesis, melena, bloody diarrhoea), gastric or intestinal ulcer with or without bleeding or perforation.
Isolated cases: aphthous stomatitis, glossitis, oesophgageal lesions, diaphragm-like intestinal strictures, lower gut disorders such as non-specific haemorrhagic colitis and exacerbation of ulceratfve colitis or Crohn's disease, constipation, pancreatitis.
Occasional: epigastric pain, other gastrointestinal disorders such as nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia.
Rare: gastrointestinal bleeding (haematemesis, melena, bloody diarrhoea), gastric or intestinal ulcer with or without bleeding or perforation.
Isolated cases: aphthous stomatitis, glossitis, oesophgageal lesions, diaphragm-like intestinal strictures, lower gut disorders such as non-specific haemorrhagic colitis and exacerbation of ulceratfve colitis or Crohn's disease, constipation, pancreatitis.

CENTRAL NERVOUS SYSTEM
Occasional: headache, dizziness, vertigo.
Rare: drowsiness.
Isolated cases: sensory disturbances, including paraesthesias, memory disturbances, disorientations, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions, aseptic meningitis.

Special senses
Isolated cases: disturbances of vision (blurred vision, diplopia), impaired hearing, tinnitus, taste disturbances

Skin
Occasional: rashes or skin eruptions.
Rare: urticaria
Isolated Cases: bullous eruptions, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome (acute toxic epidermolysis), erythroderma (exfoliative dermatitis) loss of hair, photo-sensitivity reactions; purpura, including allergic purpura.

Kidney
Rare: oedema
Isolated cases: acute renal failure, urinary abnormalities such as haematuria and proteinuria, interstitial nephritis, nephrotic syndrome, papillary necrosis.

Liver
Occasional: elevation of serum aminotransferase values.
Rare: hepatitis with or without jaundice.
Isolated cases: fulminant hepatitis.

Blood
Isolated cases: thrombocytopenia, leucopenia, haemolytic anaemia, aplastic anaemia, agranulocytosis.

Hypersensitivity
Rare: hypersensitivity reactions such as asthma, systemic anaphylactic/anaphylactoid reactions including hypotension.
Isolated cases: vasculitis, pneumonitis.

CARDIOVASCULAR SYSTEM
Isolated cases: palpitation, chest pain, hypertension, congestive heart failure.
Mechanism of action: VELFLEX contains the potassium salt of diclofenac, a non-steroidal compound with pronounced analgesic, anti-inflammatory, and antipyretic properties.
VELFLEX tablets have a rapid onset of action which makes them particularly suitable for the treatment of acute painful and inflammatory conditions. Inhibition of prostaglandin biosynthesis, which has been demonstrated in experiments, is considered to be fundamental to its mechanism of action. Prostaglandins play a major role in causing inflammation, pain and fever. Diclofenac potassium in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to the concentrations reached in humans.

PHARMACODYNAMIC EFFECTS
VELFLEX has been found to exert a pronounced analgesic effect in moderate and severe pain. In the presence of inflammation, e.g. due to trauma or following surgical interventions, it rapidly relieves both spontaneous pain and pain on movement and diminishes inflammatory swelling and wound oedema. Clinical studies have also revealed that in primary dysmenorrhoea the active substance is capable of relieving the pain and reducing the extent of bleeding.

STORAGE
Dosage as directed by physician. To be dispensed on the prescription of a registered medical practitioner only. Store below 30°C in a dry place, protect from light. Keep out of the reach of children.

PACKS
20's film coated tablets-each containing 50 mg of diclofenac potassium.
20's film coated tablets each containing 75 mg of diclofenac potassium.
20's film coated tablets each containing 100 mg of diclofenac potassium.

- **خوراک:** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰° ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.,
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

Art No.: 155/1