CLOF 100mg Tablets

(Aceclofenac)

کلوف ۱۰۰ ملی گرام گولیاں

(ایسیکلوفینک)

COMPOSITION:
CLOF 100mg tablets
Each film coated tablet contains:
Aceclofenac 100mg
(As per innovatoer's Specs.)

DESCRIPTION
CLOF (Aceclofenac) is a non-steroidal agent with excellent anti-inflammatory and analgesic properties.

PHARMACODYNAMICS
The mode of action of aceclofenac is largely based on the inhibition of prostaglandin synthesis. Aceclofenac is a potent inhibitor of the anzyme cyclo oxygenase, which is involved in the production of prostaglandins. In addition to the inhibition of prostaglandin synthesis, aceclofenac inhibits pro-inflammatory mediators, decreases adhesion moleculles expressions, inhibits Nitric Oxide production and shows antioxidant properties all these contribute to its stronganti inflammatory property.

PHARMACOKINETICS
Aceclofenac is well absorbed from the gastrointestinal tract and peak plasma concentration occurs 1 to 3 hours after an oral dose. Aceclofenac is more than 99% bound to plasma proteins. The plasma elimination half-life is about 4 hours. About two-thirds of a dose is excreted in the urine, mainly as hydroxymetabolites.

INDICATIONS
The Aceclofenac tablets is used to relieve pain and inflammation in patients suffering from:
Arthritis of the joints (osteoarthritis). This commonly causes the loss of the cartilage and bone tissue next to the joint.
Autoimmune disease that causes chronic inflammation of the joints (reheumatoid arthritis).
Arthritis of the spine which can lead to the fusion of the vertebrae (ankylosing spondylitis).

DOSAGE AND ADMINISTRATION
Aceclofenac tablets are supplied for oral administration and should be swallowed whole with a sufficient quantity if liquid. Aceclofenac should be taken preferably with or after food.

Adults: The recommended dose is 200mg daily, taken as two separate 100mg doses, one tablet in the morning and one in the evening.

Children: It is not recommended for use in children under the age of 18 years.

Elderly: The pharmacokinetics of Aceclofenac are not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency. As with other non-steriodal anti-inflammatory drugs (NSAIDS), caution should be exercised in the treatment of elderly patients, who are at increased risk of the suffering from impaired renal, cardiovascular or hepatic function and receiving concomitant medication. If an NSAID is considered necessary, the lowest effective dose should be used for the shortest possible duration. The elderly should be monitored regularly for G1 bleeding during NSAID therapy.

Renal insufficiency: There is no evidence that the dosage of Aceclofaenac needs to be. modified in patients with mild renal impairment, but as with other NSAIDS caution should be exercised.

Hepatic insufficiency: There is some evidence that the dose of Aceclofenac should be reduced in patients with hepatic impairment and it is suggested that an initial daily dose of 100mg be used.

CONTRAINDICATIONS
• Hypersensitivity to any of the constituents.
NSAIDS are contraindicated in patients who have previously shown. hypersentivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory durgs.
• Severe hepatic and cardiac failure.
• Moderate to severe renal failure.
• Active or previous peptic ulcer.
• History of upper gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

WARNINGS AND PRECAUTIONS
• Close medical surveillance is imperative in patients with symptoms indicative of gastrointestinal disorders, with a history suggestive of gastrointestinal ulceration, with ulcerative colitis or with Crohn's disease, bleeding diathesis or haematological abnormalities.
• Gastrointestinal bleeding or ulcerative perforation, haematemesis and melaena have in general more serious consequences in the elderly. They can occur at any time during treatment, with or without warning symptoms or previous history. In the rare instances, where gastrointestinal bleeding or ulceration occurs in patients receiving acelofenac, the drug should be withdrawn, close medical surveillance is also imperative in patients suffering from severe impairment of hepatic function.
• Aceclofenac should be given with caution to elderly patients with renal, hepatic or cardiovascular impairment and to those receiving. other medication. The lowest effective dose should be used and. renal function monitored regularly.
• As with other NSAIDS, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug.
• Caution should also be exercised in patients with history of coagulation defects and history of live dysfunction.
• Renal and hepatic function and blood counts should be monitored during long term treatment. Persistently elevated hepatic enzyme levels necessitate withdrawal of aceclofenac.
• All NSAIDS are contra-indicated in patients with active petic ulceration or gastrointestinal bleeding; in addition, the non- selective NSAIDs should be used with caution, if at all in patients with a history of such disorders.
• To reduce the risk of gastrointestinal effects, NSAIDs may be taken with or after food or Milk. Histamine H2-antagonist, proton pump inhibitors such as omeprazole, or misoprostol may be used for a similar purpose in high risk patients taking non-selective NSAIDS.
• NSAIDS should be used with caution in patients with chronic disease or ulcerative colitis as there conditions may be exacerbated.
• All NSAIDs are contra-indicated in severe heart failure.
NSAIDS should also be use with caution in patients in hypertension, left ventricular dysfunction, oedema or a history of cardiac failure, and in those with other risk factors for developing cardiovascular events.
Other non selective NSAIDS should be used with caution in uncontrolled hypertension, heart failure, ischemic heart disease, peripheral arterial disease, cererovascular disease and when used long term in patients with risk factors for cardiovascular events. NSAIDS should be used with caution in patients with infections, since symptoms such as fever inflammation may be masked (for the suggestion that they should not be used in children with varicella see below).
• They should also be used with caution in patients with asthma allergic disorders.
• NSAIDs (including topic NSAIDS) are contra-indicated in patients with the history of hypersensitivity reactions to such drugs, including those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAIDS.
• Other general precautions to be observed include use in patients with haemorhagic disorders, connective tissue disorders or impaired renal or haptic function.
• Patient undergoing therapy with some NSAID may need to be monitored for development of blood, kidney, liver or eye disorders
• NSAID should be used with caution in the elderly and may need to be given in reduced doses.

DRUG INTERACTIONS
Drug interactions associate with aceclofenac are similar to those observed with other NSAIDS.
• Interactions involving NSAIDS include enhancement of the effects of oral anticoagulants (especially by azapropazone and phenylbutazone) and increased plasma concentrations of lithium, methotrexate, and cardiac glycosides.
• The risk of nephrotoxicty may be increased if given with ACE inhibitors, cyclosporin, tacrolimus or diuretics. Effects on renal function may lead to reduced excretion of some drugs.
• There may also be an increased risk of hyperkalaemia with ACE inhibitors, cyclosporin, tacrolimus or diuretics. Effects on renal function may lead to reduced excretion of some drugs.

• There may also be an increased risk of hyperkalaemia with ACE inhibitors and some diuretics including potassium sparing diuretics.
• The antihypertensive effects of some antihypertensive including ACE inhibitors, beta blockers and diuretics may be reduced.
• Convulsions may occure due to an interaction with quinolones.
• NSAIDS may increased the effects of phenytion and sulfonylurea antidiabetics.
• Use of more that one NSAID together (including asprin) should be avoided because of the increase risk of adverse effects.
• The risk of gastrointestinal bleeding and ulceration associated with NSAIDS is increased when used with corticosteroids, the SSRIs, the SNRI venlafaxine, the antiplatelets clopidogrel and ticlopidine, iloprost, erlotinib, sibutramine, or possibly alcohol, bisphophonates, or pentoxofylline.
• There may be an increased risk of haematotoxicity if zidovudine is used with NSAIDS Ritonavir may have increased the plasma concentrations of NSAIDs.
• These have been occasional reports of increased adverse effects when NSAIDS were given with misoprostol although such combinations have sometimes been used to decrease the gastrointestinal toxicity of NSAIDS or corticosteroids may result in increased frequency of side effects.
• Caution should be exercised if NSAID and methotrexate are administered with 2-4 hours of each other since NSAID-may increased methotrexate plasma level, resulting in increased toxicity.

Renal Impairment:
Patients with mild renal impairment should be kept under surveillance since the use of NSAIDS may result in deterioration of renal function. The lowest effective dose should be used and renal function monitored regularly.

Hepatic Impairment:
Dose of aceclofenac should be reduced in patients with impaired liver function, If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilla, rash), aceclofenac should be discontinued. Hepatitis may occur without prodromal symptoms.

Pregnancy:
There is no information on use of aceclofenac in pregnant patients therefore the drug is not recommended in pregnant women.

Lactation:
Aceclofenac is not recommended in lactating women.

Pediatric use:
There are no clinical data on the use of aceclofenac in children.

ADVERSE EFFECTS
Like all medicines, Aceclofenac tablets can cause side effects, although not everybody gets them.
The possible adverse effects are as; aceclofenac is associated with a small increased risk of heart attack, (myocardial infarction) or stroke, sever allergic reaction (anaphylactic shock). The symptoms of allergic reaction may include difficulty breathing, wheezing, abnormal pain and vomiting, skin rash, flaking skin, boils or sore lips and mouth. The very rarely signs of allergic reaction may include sudden wheeziness fluttering or tightness in the chest and collapse. The other noted adverse effects are swelling of the face, kidney failure, Indigestion or heartburn, Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
Dizziness, indigestion, abdominal pain, nausea (feeling sick), diarrhea, increase liver enzymes in the blood, wind (flatulence), inflammation of the lining of the stomach (gastritis), constipation, vomiting, mouitching, rash, inflammation of the skin (dermatitis), raised circular singing or burning patches on the skin (hives), increase in blood increase in blood creatinine levels, low levels of iron in the blood, hyper (allergic reaction), swelling, visual disturba nce, shortness of breath, he high blood pressure, gastrointestinal (stomach) bleeding, gastrointestinal (stomach) ulcer, low white blood cells levels, low platelets levels in decreased bone marrow function, abnormal breakdown of red blood (anemia), high potassium levels in the blood, depression, strange inability to sleep, tingling, pricking or numbness of skin, uncontrollable (tremor), drowsiness, headaches, abnormal taste in the mouth, sel spinning when standing still, heart pounding or racing (palpitations). difficulty breathing, high pitched noise when breathing, inflammation mouth, stomach ulcer, inflammation of the pancreas (pancreatitis), infl of the liver (hepatitis), yellowing of the skin (jaundice), spontaneous ble the skin (appears as a rash), blisters, water retention and swelling, tire cramps, increased blood alkaline phosphatase levels, weight gain, ringing in the ears, swelling, redness, and pain in a blood vessel, Crohn (inflammation of the lining of the digestive system) and Kidney failure. The other side effects that have been reported with this type of drug are; bone marrow failure, hallucinations, confusion, blurred, partial of loss of vision, painful movement of the eye, ringing in the ears, a asthma, ulcers, perforation of either the stomach, large intestine or blistering and peeling of the top layer of skin, mild, itchy pink/redness reddening or scaling of skin, skin irritation (eczema), skin reaction to inflammation of the kidneys, generally feeling unwell, aseptic exacerbation of colitis and Crohn's disease, hypertension (high blood and cardiac failure, bone marrow depression.

OVERDOSAGE
The management of the acute poisoning with NSAIDs essentially supportive and symptomatic measures.

DOSAGE
As per directed by the physician.

INSTRUCTIONS
Store at 25°C (excursion permitted between 15°C-30°C)
Protect from sunlight and moisture. Keep all medicine out of reach of children.

To be sold and used on prescription of a registered medical practitioner only.

PACK SIZE: CLOF tablet 100mg pack of 30 tablets

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: ۲۵ ڈگری سینٹی گریڈ درجہ حرارت پر رکھیں۔

(درجہ حرارت کی حد ۱۵ تا ۳۰ ڈگری سینٹی گریڈ ہے)

دھوپ اور نمی سے بچائیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:
SHROOQ PHARMACEUTICALS (PVT) LTD.
21-Km Feroz Pur Road, Lahore-Pakistan.

Marketed by:
CENRJY Pharmaceuticals