CHAPHA
PATIENT-CENTRIC SOLUTIONS

CLOREN 12.5 mg

Suppositories

COMPOSITION
Each suppository contains:

Active ingredient:
Diclofenac sodium .....12.5 mg

Excipient:
Hard fat.

PHARMACOTHERAPEUTIC GROUP
Non-steroidal anti-inflammatory drugs (NSAIDs).

INDICATIONS
CLOREN relieves pain and reduces inflammation (swelling and redness).
CLOREN is used to treat a number of painful conditions including:
- Different types of arthritis including rheumatoid arthritis and osteoarthritis.
- Other painful conditions where swelling is a problem such as back pain, rheumatism, muscle strains, sprains and tendonitis (e.g. tennis elbow).
- Menstrual cramps (period pain).
- Migraine attacks.
- Acute attacks of gout.
  Post-traumatic and post-operative pain, inflammation, and swelling, e.g. following dental or orthopaedic surgery.
- As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis.

DOSAGE
As a general recommendation, the dose should be individually adjusted and the lowest effective dose should be given for the shortest possible duration.
Children aged 1 year or over and adolescents should be given 0.5 to 2 mg/kg body weight daily in 2 to 3 divided doses, depending on the severity of the disorder.
For treatment of juvenile rheumatoid arthritis, the dose can be raised up to a maximum of 3 mg/kg daily, given in divided doses.
Try not to go to the toilet and open your bowels for at least one hour after using the suppository.

CONTRAINDICATIONS
- Known hypersensitivity to the active substance or to the excipient.
- Like other non-steroidal anti-inflammatory drugs (NSAIDs), CLOREN is also contraindicated in patients in whom attacks of asthma, angioedema (swelling of the face and mouth), skin rash, runny nose or any other allergic-type reactions are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.
- Active gastric or intestinal ulcer or bleeding in the digestive tract.
- Patients with inflammatory lesions of the rectum or anus and in patients with a recent history of rectal or anal bleeding.
- Last trimester of pregnancy.
- Severe hepatic, renal or cardiac failure.
- Heart bypass surgery.

WARNINGS AND PRECAUTIONS
Tell your doctor if you have any of the following medical conditions:
Past history of ulcers (gastric or duodenal).
Gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.
Diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative or ischemic colitis).
Past history of hemorrhoids or irritation of the rectum.
Established disease of the heart or blood vessels (including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, peripheral arterial disease or atherosclerotic cardiovascular disease).
Risk factors for cardiovascular disease such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in the blood, diabetes.
Porphyria.
Bleeding disorders or other blood disorder (e.g. anemia).
Asthma or any other chronic lung disease that causes difficulty in breathing (such as chronic obstructive pulmonary disease).
Hay fever (Seasonal allergic rhinitis).
Repeated chest infections.
Polyps in the nose.
Liver or kidney problems.

INTERACTIONS
CYP2C9 inhibitors (such as sulfinpyrazone, voriconazole)
Coadministration could result in a significant increase in peak plasma concentrations and exposure to diclofenac.
CYP2C9 inducers (such as rifampicin)
Coadministration could result in a significant decrease in plasma concentration and exposure to diclofenac.
Lithium
Diclofenac may raise plasma concentrations of lithium.
Digoxin
Diclofenac may raise plasma concentrations of digoxin.
Diuretics and antihypertensive agents (beta-blockers, angiotensin converting enzyme inhibitors)
Diclofenac may cause a decrease in their antihypertensive effect.
Other NSAIDs and cortiocosteroids
Concomitant administration of diclofenac and other systemic NSAIDs (e.g. aspirin, salicylates or ibuprofen) or corticosteroids may increase the frequency of gastrointestinal undesirable effects.
- *Anticoagulants and anti-platelet agents*
  Concomitant use may increase the risk of bleeding.
- *Selective serotonin reuptake inhibitors (SSRIs)*
  Concomitant administration may increase the risk of gastrointestinal bleeding.

Antidiabetics
Diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of both hypoglycemic and hyperglycemic effects. There have also been isolated reports of metabolic acidosis when diclofenac was coadministered with metformin.

Cyclopsorin and Tacrolimus
Diclofenac may increase the nephrotoxicity of cyclosporin and tacrolimus.
Methotrexate
Caution is recommended when NSAIDs, including diclofenac, are administered less than 24 hours before or after treatment with methotrexate, since blood concentrations of methotrexate may rise.
Drugs known to cause hyperkalemia (potassium-sparing diuretics, cyclosporin, tacrolimus or trimethoprim)
Concomitant treatment may be associated with increased serum potassium levels.
Quinolones antibacterials
There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.
Phenytoin
There is an expected increase in exposure to phenytoin when using phenytoin concomitantly with diclofenac.

OVERDOSE
Symptoms
There is no typical clinical picture resulting from diclofenac overdosage. Overdosage can cause symptoms such as vomiting, gastrointestinal hemorrhage, diarrhea, dizziness, ringing in the ears or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.
Therapeutic measures
Management of acute poisoning with NSAIDs, including diclofenac, essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression.

SIDE EFFECTS
Like all medicines, CLOREN can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:
Common side effects (may affect between 1 and 10 in every 100 patients):
Headache, dizziness, vertigo, nausea, vomiting, diarrhea, indigestion, pain in the stomach, wind, loss of appetite, raised level of liver enzymes in the blood, skin rash, irritation or discomfort in the rectum (back passage).
Uncommon side effects (may affect between 1 and 10 in every 1000 patients):
Fast or irregular heart beat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure).
Rare side effects (may affect between 1 in every 1000 to 1 in every 10,000 patients):
Stomach ulcers or bleeding, gastritis, vomiting blood, diarrhea with blood in it or bleeding from the back passage, black, tarry faeces or stools, drowsiness, tiredness, skin rash and itching, fluid retention (symptoms of which include swollen ankles), liver function disorders, including hepatitis and jaundice, asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest), hypersensitivity, anaphylactic and anaphylactoid reactions.
Very rare side effects (may affect less than 1 in every 10,000 patients):
Effects on the nervous system: meningitis, tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, convulsion, headaches together with a dislike of bright lights, fever and a stiff neck.
Effects on the stomach and digestive system: Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease), inflammation of the pancreas.
Effects on the chest or blood: Hypertension, hypotension, inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).
Effects on the liver or kidneys: Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.
Effects on skin or hair: Facial swelling, serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight. Hair loss.
Effects on the reproductive system: Impotence.

CONSERVATION
Store below 30°C.
Keep out of the reach of children.

Marketing Authorization Holder: **Chaoul Pharmaceuticals (CHA-PHA) S.A.L**.– Lebanon

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