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Dolotec CR

(Naproxen Sodium)

750mg Tablets

ڈولوتیک سی آر

(نپروکسن سوڈیم)

۵۰۰ ملی گرام گولیاں

Composition:

Each film coated extended-release tablet contains:
Naproxen Sodium 825mg eq. to Naproxen750mg

WARNING

Cardiovascular Risk

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
- Naproxen is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly people are at greater risk for serious gastrointestinal events.

CLINICAL PHARMACOLOGY

Mechanism of Action:

Naproxen is a nonsteroidal anti-inflammatory drug (NSAID), with analgesic and antipyretic properties. As with other NSAIDs, its mode of action is not fully understood; however, its ability to inhibit prostaglandin synthesis may be involved in the anti-inflammatory effect.

PHARMACOKINETICS

Absorption

Absorption Naproxen itself is rapidly and completely absorbed from the GI tract with an in vivo bioavailability of 95%. Based on the pharmacokinetic profile, the absorption phase of DOLOTEC Tablets occurs in the first 4-6 hours after administration.

Distribution

Naproxen has a volume of distribution of 0.16 L/kg. At therapeutic levels, naproxen is greater than 99% albumin-bound. At doses of naproxen greater than 500 mg/day, there is a less than proportional increase in plasma levels due to an increase in clearance caused by saturation of plasma protein binding at higher doses. However, the concentration of unbound naproxen continues to increase proportionally to dose. DOLOTEC Tablets exhibit similar dose proportional characteristics.

Metabolism

Naproxen is extensively metabolized to 6-O-desmethyl naproxen and both parent and metabolites do not induce metabolizing enzymes.

Elimination

The elimination half-life of DOLOTEC CR Tablets and conventional naproxen is approximately 15 hours. Steady state conditions are attained after 2-3 doses of DOLOTEC Tablets. Most of the drug is excreted in the urine, primarily as unchanged naproxen (less than 1%).

INDICATIONS:

DOLOTEC CR Tablets are indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, tendinitis, bursitis and acute gout. It is also indicated in the relief of mild to moderate pain and the treatment of primary dysmenorrhea.

SPECIAL POPULATION Pregnancy Do not take this medicine during the last 3 months of pregnancy, as it may harm your unborn baby or cause problems during delivery. If you are in the first 6 months of pregnancy, take this medicine only if your doctor considers it necessary and advises you to do so. If you become pregnant while taking this medicine, inform your doctor immediately. Breast-feeding Naproxen does pass into the mother's milk; therefore, breast feeding should be avoided if taking Naproxen Tablets. Fertility Naproxen Tablets may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant. Children and Adolescents The safety and effectiveness of this medicine in children have not been established. It should not be used in children unless recommended by a doctor. Elderly Patients Elderly patients may be more likely to experience side effects, particularly stomach bleeding, kidney problems, heart problems, or other serious adverse effects. Your doctor may prescribe the lowest effective dose and monitor you regularly during treatment. DOSAGE & ADMINISTRATION For rheumatoid arthritis, osteoarthritis and ankylosing spondylitis 250-500mg taken at 12-hour intervals. Acute musculoskeletal disorders 500mg to start with, followed by 250mg every 6-8 hours. Do not take more than 1250mg (i.e., five 250mg tablets) in any 24-hour period. Acute gout 750mg to start with, followed by 250mg every 8 hours until the attack has passed. The elderly Elderly patients are more likely to experience side effects. Therefore, treatment should be started on the lowest possible dose for the shortest possible duration. Your doctor should monitor your condition regularly. Use in children If Naproxen Tablets are prescribed for a child make sure that the tablets are taken as instructed by the doctor. Naproxen is not recommended for children under 16 years of age for use other than in the treatment of juvenile rheumatoid arthritis. For juvenile rheumatoid arthritis a dose of 10mg per kg body weight per day should be given in two doses, once every 12 hours. You should have enough to drink to stay well hydrated while taking this medicine, particularly important for people having kidney problems. ROUTE OF ADMINISTRATION For oral administration only. ADVERSE REACTIONS Serious stomach or gut problems, signs include: • Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds. • Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhea. • Ulcers or holes forming in your stomach or gut. Signs include upset stomach, stomach pain, fever, feeling or being sick. • Problems with your pancreas. Signs include severe stomach pain which spreads to your back. • Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhea, vomiting and weight loss. Allergic reactions, signs include: • Sudden swelling of your throat, face, hands or feet. • Difficulty breathing, tightness in your chest. • Skin rashes, blisters or itching. Severe skin rashes, signs include: • A severe rash that develops quickly, with blisters or peeling of skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time. • Blistering of skin when exposed to sunlight (porphyria cutanea trade) seen most on arms, face and hands. Liver problems, signs include: • Yellowing of your skin or the whites of your eyes (jaundice). • Feeling tired, loss of appetite, feeling or being sick and pale-colored stools (hepatitis) and problems (including hepatitis), shown in blood tests. Heart attack, signs include: • Chest pain which may spread to your neck and shoulders and down your left arm. Stroke, signs include: • Muscle weakness and numbness. This may only be on one side of your body. • A suddenly altered sense of smell, taste, hearing or vision, confusion. Meningitis, signs include: • Fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus'). Other possible side effects: Stomach and gut • Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhea, wind. Blood • Blood problems, like anemia or changes to the numbers of white blood cells. Mental illness • Having difficulty sleeping or changes in your patterns of dreaming. • Depression. • Confusion or seeing and possibly hearing things that are not there (hallucinations). Nervous system • Headache. • Fits or seizures, feeling dizzy or light-headed or sleepy. • Pins and needles or numbness of your hands and feet. • Difficulty with your memory or concentration. Eyes and ears • Changes to your eyesight, eye pain. • Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss. • Dizziness that causes problems with your balance. Heart and circulation • Swelling of your hands, feet or legs (oedema), this may be with chest pains, tiredness, shortness of breath (cardiac failure). • A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure. • Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain. Chest • Difficulty breathing, including shortness of breath, wheezing or coughing. • Pneumonia or swelling of your lungs. Skin and hair • Skin rashes including redness, hives, pimples and blisters on your body and face. • Bruising, itching, sweating, skin being more sensitive to the sun or hair loss. Urinary • Blood in your water (urine) or kidney problems. Other • Thirst, fever, feeling tired or generally unwell. • A sore mouth or mouth ulcers.	Page No. 02
	Page No. 03

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- Muscle pain or weakness.
- Problems for women in getting pregnant.
- Systemic lupus erythematosus (SLE). Signs include fever, rash, problems with your kidneys and joint pain.

CONTRAINDICATIONS

DOLOTEC is contraindicated in patients with known hypersensitivity to naproxen. DOLOTEC should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal anaphylactic-like reactions to NSAIDs have been reported in such patients. DOLOTEC is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS AND PRECAUTIONS

Naproxen Tablets if you:

- Suffer from asthma or allergies (like hay fever) or have had swelling of the face, lips, eyes or tongue in the past
- Feel weak (perhaps because of an illness) or you are an older person
- Have lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked or itchy nose (rhinitis)
- Have problems with your kidneys or liver
- Have problems with the way your blood clots
- Have problems with the blood vessels (arteries) anywhere in your body
- Have too much fat (lipid) in your blood (hyperlipidemia)
- Have an autoimmune condition, such as 'systemic lupus erythematosus' (SLE, causes joint pain, skin rashes and fever) and colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhea, vomiting and weight loss) Have heart problems (high blood pressure, previous stroke).

Medicines such as naproxen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If you have heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist. Serious skin reactions including (Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported in association with naproxen. Stop using naproxen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions.

EFFECT OF OTHER DRUGS ON NAPROXEN.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- Other pain killers like aspirin, ibuprofen, diclofenac and paracetamol.
- A diuretic (water tablet used for high blood pressure), like furosemide
- Medicines for high blood pressure
- Digoxin for heart conditions
- Lithium or SSRIs (Selective Serotonin Reuptake Inhibitors) such as fluoxetine or paroxetine used for treatment of depression
- Prednisolone, hydrocortisone and dexamethasone a steroid treatment for inflammation
- Methotrexate used to treat rheumatoid arthritis
- Ciclosporin, tacrolimus which are medicines used to suppress the immune system
- Ciprofloxacin, sulphonamides such as sulphamethoxazole, antibiotics used to treat bacterial infections Mifepristone used in pregnancy terminations (at any time within the last 12 days)
- Zidovudine used for the treatment of AIDS and HIV infections
- Anti-inflammatory pain killers such as ibuprofen or ibuprofen preparations that can be bought without a prescription
- Phenytoin used to treat epilepsy
- Gliclazide or glibenclamide (sulphonylureas) used to treat diabetes
- Probenecid used to treat gout
- Aspirin/acetysalicylic acid, clopidogrel, warfarin, heparin, ticlopidine, dipyridamole which are anti-platelet agents used to prevent blood clots
- Colestyramine used to treat high levels of cholesterol in the blood
- Medicines used as antacids
- Angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan.

OVERDOSAGE

If you or someone else has taken more of this medicine than prescribed, contact your doctor

or go to the nearest hospital immediately. Take the medicine pack with you if possible.

Symptoms of an overdose may include:

- Drowsiness or unusual sleepiness
- Nausea or vomiting
- Stomach pain or discomfort
- Heartburn or indigestion
- Bleeding from the stomach or intestines (which may appear as black stools or vomiting blood)
- Less commonly, high blood pressure, kidney problems, difficulty breathing, seizures, or loss of consciousness.

There is no specific antidote for naproxen overdose. Treatment will depend on your symptoms and may include measures to reduce absorption of the medicine if the overdose is recognized soon after it is taken. Dialysis is not effective in removing naproxen from the body.

PRESENTATION

Dolotec CR Tablet is available in blister packs of 1x10's

Dosage:

As directed by the physician.

Instructions:

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

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایت : دو کو ۳۰ کو 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۔

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