PORTO

(Piroxicam Beta Cyclodextrin)
20mg Tablets

پورٹو ۲۰ ملی گرام گولیاں

DESCRIPTION:
PORTO (Piroxicam Beta Cyclodextrin) is the first nonsteroidal anti-inflammatory agent, which also possesses analgesic and antipyretic properties, in which the active substance is complexed with the cyclic, oligosaccharide cyclodextrin, which acts as an artificial receptor. The beta cyclodextrin acts like a molecular size capsule that envelopes the poorly soluble piroxicam, improves its solubility and speeds absorption. This offers the potential advantage of a more rapid onset of effect and better tolerability due to reduced contact time with the GI mucosa.

QUALITATIVE AND QUANTITATIVE COMPOSITION:
PORTO (Piroxicam) is available for oral administration as
PORTO 20mg Tablet
Each tablet contains:
Piroxicam beta cyclodextrin 191.2mg equivalent to Piroxicam USP.....20mg
(Product Specs.: Sigma)

CLINICAL PHARMACOLOGY:

Mechanism of Action:
Piroxicam; a NSAID complex with cyclodextrin possesses analgesic and antipyretic properties, the complex allows single molecule of NSAID to be released adjacent to the gastrointestinal mucosa, instead of crystals. Since the time contact with gastric mucosa is reduced, the risk of direct contact gastric irritation is also reduced.

Pharmacokinetics:
Piroxicam beta cyclodextrin dissociates in the gastrointestinal tract to piroxicam and beta cyclodextrin.

Piroxicam absorption from piroxicam beta cyclodextrin is more rapid than that of unmodified piroxicam. Piroxicam is well absorbed from the gastrointestinal tract and peak plasma concentrations of piroxicam are reached 30 to 60 minutes after an oral dose. Beta cyclodextrin is not absorbed but is metabolized in the colon to various sugars. Piroxicam is 99% bound to plasma proteins.

Piroxicam has a long plasma elimination half life of about 50 hours. It is metabolized in the liver by hydroxylation and conjugation with glucuronic acid. Excreted mainly in the urine with smaller amounts in feces.

THERAPEUTIC INDICATIONS:
PORTO (Piroxicam) is indicated for a variety of acute painful conditions requiring anti-inflammatory and analgesic activity including;
–Rheumatoid Arthritis
–Osteo-Arthritis (Arthrosis, Degenerative Joint Disease)
–Ankylosing Spondylitis
– Musculoskeletal and Joint Disorders
–Gout
–Soft-Tissue Disorders
–Post-Operative Pain

DOSAGE AND ADMINISTRATION:
–In rheumatic disorders a usual initial dose of **PORTO** (Piroxicam) is 20mg daily as a single dose. Daily maintenance doses may vary between 10mg and 30mg given in single or divided doses.
–In acute musculoskeletal conditions, an initial dose of 40mg daily may be given for two days followed by 20mg daily for a total of 1 to 2 weeks.
–In acute gout, the usual dose being 40mg daily for 5 to 7 days.
–Post operative pain following dental or minor surgery, the dose is 20mg daily. Higher doses of 40mg daily for the first two days are recommended following orthopedic surgery.

Special Population:
Geriatric Patient:
Daily dose of 10mg is recommended in elderly patients.

CONTRAINDICATIONS:
PORTO should not be used in the following:
–Known hypersensitivity to the drug
–Gastroduodenal ulcer, gastritis, dyspepsia, severe hepatic or renal disturbances, severe heart failure, severe hypertension, severe blood alterations or hemorrhagic diathesis.
–Piroxicam must not be administered to patients in whom acetylsalicylic acid or other NSAIDs induce the symptoms of asthma, rhinitis or urticaria
–Ascertained or suspected pregnancy, during lactation and in children under 12 years.

PRECAUTIONS:
Use **PORTO** with caution in;

Patients at greatest risk of complications due to impaired hepatic or renal function with heart failure, taking diuretics or the elderly. As NSAIDS inhibit the synthesis of renal prostaglandin which plays a supportive role in the maintenance of renal perfusion, patients with a medical history of disturbances in the upper GI tract as serious gastrointestinal toxicity such as bleeding, ulceration and perforation can occur at any time with chronic NSAID therapy, patients with asthma because bronchial smooth muscle spasm may be aggravated by prostaglandin inhibition, patients with compromised cardiac function as edema has been reported during piroxicam treatment.

Use **PORTO** under close supervision in;

Patients with hypertension as the antihypertensive effect of thiazide diuretics and â-blocking agents is antagonized by NSAIDS, patients with a history of impaired renal function and periodic renal function tests carried out

Discontinue **PORTO** if;

Severe hepatic reactions including jaundice and cases of fatal hepatitis develops, abnormal liver function tests persist or worsen, clinical signs consistent with hepatic disease develop, systematic manifestations occur (e.g. eosinophilia, rash).

-Patients experiencing dizziness should refrain from driving a vehicle or operating machinery

-Piroxicam, decreases platelet aggregation and prolongs bleeding; this should be remembered when hematological tests are carried out and when patients undergo concomitant treatment with drugs that inhibit platelet aggregation and

-in patients undergoing surgery or with hemorrhagic disorders

-Anti-inflammatory, antipyretic and analgesic effects of piroxicam may mask the signs of infection (pain, fever etc.)

-Patients who develop visual disturbances during treatment with **PORTO** should have an ophthalmologic examination

Pregnancy:
PORTO should not be used in pregnant women or those likely to become pregnant unless the expected benefits outweigh the potential risk.

Nursing Mothers:
Piroxicam is not recommended for breastfeeding mothers.

DRUG INTERACTIONS:

Warfarin:
The concurrent use of NSAIDs and warfarin has been associated with severe sometimes fatal hemorrhage. Piroxicam should be used in combination with warfarin only if absolutely necessary and under close supervision.

Protein Bound Drugs:
Piroxicam is highly protein bound and therefore might be expected to displace other protein bound drugs. The physician should closely monitor dosage of following drugs concomitantly with piroxicam. Such drugs include coumarin anticoagulants, hydantoins, sulphonamides and sulfonylureas. Bleeding has been reported rarely when piroxicam, have been administered to patients on coumarin type anticoagulan

Methotrexate:
Extreme care should also be exercised in giving methotrexate to patients on piroxicam therapy because lethal Interactions have been reported between NSAIDS and methotrexate.

Aspirin and other NSAIDs:
Administration of piroxicam and aspirin reduced the plasma levels of piroxicam. The use of piroxicam with aspirin or with other NSAIDs increases the potential for adverse reactions and therefore concomitant use of two or more NSAIDs is not recommended.

Plasma Lithium Concentrations:
Piroxicam have been shown to decrease the renal clearance and increase steady state plasma concentrations of lithium. Plasma lithium concentrations should be monitored.

Diuretics:
Piroxicam may cause sodium, potassium and fluid retention and may interfere with the natriuretic action of diuretic drugs causing a reduction in diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs. These properties should be kept in mind when treating patients with compromised cardiac function of hypertension, to avoid a possible worsening of these conditions

Anti-Hypertensives:
There may be a reduction in the effect of antihypertensives.

Cardiac Glycosides:
NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycosides.

Quinolone Antibiotics:
Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Cyclosporine:
NSAIDs may increase cyclosporine nephrotoxicity as a result of their effect on renal prostaglandins.

Corticosteroids:
There is an increased risk of gastrointestinal bleeding with corticosteroids.

Aminoglycosides:
Reduction in renal function in susceptible individuals, decreased elimination of aminoglycosides and increased plasma concentrations have been reported.

Oral Hypoglycemic Agents:
Inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased risk of hypoglycemia is known to occur with oral hypoglycemic agents

ADVERSE REACTIONS:
Very common: Nausea, epigastric distress, abdominal pain and discomfort, flatulence, constipation and diarrhoea. Other possible reactions are hypersensitivity signs, such as skin rash, headache, vertigo, blood chemistry modifications, and increase in blood urea.
Less common: Vomiting, allergic oedema of the face and hands, blurred vision, tinnitus, blood chemistry alteration, increase in parameters of liver functions, jaundice, acute renal insufficiency, or cardio circulatory disorders. Sporadic cases of gastric ulcer with perforation, Stevens-Johnson's syndrome, stomatitis, alopecia and nail growth disorders have been reported.
Rare: Gastric ulcers and hemorrhages may also occur.

OVERDOSAGE:
In the event of an overdose with **PORTO**, supportive and symptomatic management is necessary and may include gastric lavage and the use of oral activated charcoal to reduce absorption of piroxicam. The correction of severe electrolyte abnormalities may need to be considered.

INSTRUCTIONS:
–Store below 30°C.
–Protect from light and moisture.
–Keep out of reach of children.
To be sold on prescription of a registered medical practitioner only.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

HOW SUPPLIED:
PORTO (Piroxicam Beta Cyclodextrin) Tablets 20mg are available in pack of 20's.

SIGMA PHARMA
Manufactured by:
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