Front

PEXY™

(Piroxicam β-Cyclodextrin)

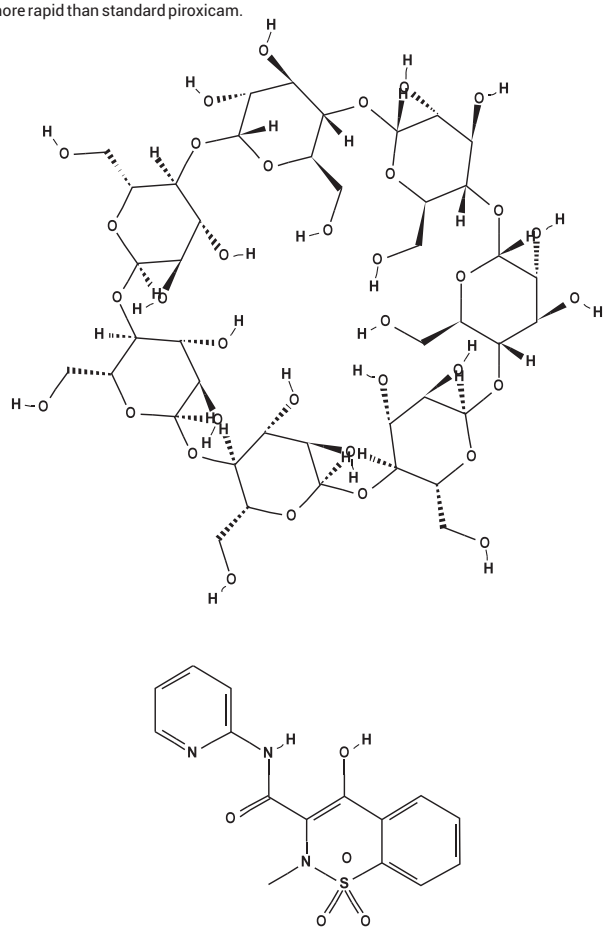
Tablet 20 mg

پیکسی

COMPOSITION:
Each film coated tablet contains:
Piroxicam (as β-Cyclodextrin) ..... 20 mg.

Product Specs.: In-house

DESCRIPTION:
Piroxicam β-cyclodextrin is the product of supermolecular encapsulation of piroxicam with the cyclic oligosaccharide β-cyclodextrin. Its action as an analgesic is more rapid than standard piroxicam.



MECHANISM OF ACTION:
PEXY is a new formulation of piroxicam as a complex with β-cyclodextrin. β-Cyclodextrin is produced by enzymatic hydrolysis of common starch, has a particular chemical structure that enables it to form inclusion compounds (molecular encapsulation) with various drugs. In this way, it Is able to improve solubility, stability and bioavailability. Pexy is very soluble in water and has a more rapid and complete absorption than plain piroxicam. The improved solubility leads to a rapid increase in plasma levels and peak value is reached earlier. Clinically, this means a quicker and more Intense analgesic and anti-inflammatory effect. The long half-life of PEXY, is the same as that of plain piroxicam and has convenient single dally dose.

PHARMACOKINETICS:
Piroxicam β-cyclodextrin dissociates in the gastrointestinal tract to piroxicam and β-cyclodextrin. Piroxicam absorption from piroxicam β-cyclodextrin is more rapid than that of unmodified piroxicam. Piroxicam is well absorbed from the gastrointestinal tract, peak plasma concentrations of piroxicam are reached 30 to 60 minutes after an oral dose. β-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. Because of this steady state conditions are not reached for 7 to 12 days; it is metabolized in the liver by hydroxylation and conjugation with glucuronic acid and excreted mainly in the urine with smaller amounts in feces. Enterohepatic recycling occurs. Less than 5% of the dose is excreted unchanged in the urine and feces.

INDICATIONS:
PEXY (Piroxicam β-cyclodextrin) 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, in soft-tissue disorders and in post-operative pain.

DOSAGE AND ADMINISTRATION:
- The prescription of piroxicam should be initiated by physicians with experience in the diagnostic evaluation and treatment of patients with inflammatory or degenerative rheumatic diseases. The maximum recommended daily dose is 20 mg.
- For Rheumatic disorders, a usual initial dose is 20 mg once a day. Daily maintenance doses may vary between 10 mg and 30 mg given in single or divided doses.
- Acute musculoskeletal conditions, an initial dose of 40 mg daily may be given for 2 days followed by 20 mg daily for a total of 1 to 2 weeks.
- Acute gout, the usual dose is 40 mg daily for 5 to 7 days.
- In the treatment of post-operative pain, following dental or minor surgery, the dose is 20 mg daily. Higher doses of 40 mg daily, for the first 2 days, are recommended following orthopedic surgery. The dose may be reduced to 10 mg daily in elderly patients.
- To be taken preferably with or after food. The benefit and tolerability of treatment should be reviewed within 14 days.

WARNINGS & PRECAUTIONS:
Renal impairment:
- NSAIDs inhibit the synthesis of renal prostaglandin which plays a supportive role in the maintenance of renal perfusion in patients whose renal blood flow and blood volume are decreased. Particular caution must be taken in patients at greatest risk of this complication include those with impaired hepatic or renal function, with heart failure, taking diuretics or the elderly. Such patients should be carefully monitored while receiving NSAID therapy.
- Blood urea nitrogen elevation has been observed in some patients which may not be associated with elevations in serum creatinine. As with other NSAIDs, it is recommended that piroxicam be given under close supervision in patients with a history of impaired renal function and periodic renal function tests carried out. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with piroxicam.

Hepatic impairment:
- Although such reactions are rare, if abnormal liver function tests persist or worsen, if clinical signs consistent with hepatic disease develop or if systemic manifestations occur (e.g., eosinophilia, rash) piroxicam should be discontinued.

Gastrointestinal tract:
Serious gastrointestinal toxicity such as bleeding, ulceration and perforation can occur anytime with or without warning symptoms, in patients treated chronically with NSAID therapy. Piroxicam must be used under strict medical control in patients with a medical history of disturbances in the upper gastrointestinal tract. The possible need for combination therapy with gastro-protective agents (e.g. misoprostol or proton pump inhibitors) should be carefully considered.
Asthma: Piroxicam should be used with caution in patients with asthma because bronchial smooth muscle spasm may be aggravated by prostaglandin inhibition.
Hypertension: As with other NSAIDs, piroxicam should be given under close supervision to patients with hypertension as the antihypertensive effect of thiazide diuretics and b -blocking agents is antagonized by NSAIDs.
Compromised cardiac function: Edema, mainly ankle edema, has been reported during piroxicam treatment; as with other non-steroidal anti-inflammatory agents, piroxicam should be used with caution in patients with compromised cardiac function.
Bleeding time: Piroxicam, like other NSAIDs, 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.
Masking infection:As with other NSAIDs, anti-inflammatory, antipyretic and analgesic effects of piroxicam may mask the signs of infection (pain, fever, etc.).
Ophthalmologic monitoring: Adverse ophthalmologic effects have been observed with NSAIDs. Patients who develop visual disturbances during treatment with piroxicam should have an ophthalmologic examination.
Effects on ability to drive or use machinery: Patients experiencing dizziness or other central nervous system disturbance should refrain from driving a vehicle or operating machinery.

SPECIAL POPULATION:
Pregnancy: Piroxicam should not be used in pregnant women or those likely to become pregnant unless the expected benefits outweigh the potential risk.
Nursing mothers: Piroxicam appeared in breast milk in a concentration approximately 1 to 3% of that reached in maternal plasma. Piroxicam is not recommended for breastfeeding mothers unless the expected benefits outweigh any potential risk, as clinical safety has not been demonstrated.
Pediatric use: The use of piroxicam in children under 12 years is not recommended as safety and efficacy in this age group are not established.

DRUG INTERACTIONS:
Aspirin and other NSAIDs: Administration of piroxicam and aspirin reduced the plasma levels of piroxicam to about 80% of the normal value. The use of piroxicam with aspirin or its concurrent use with other NSAIDs increases the potential for adverse reactions and therefore concomitant use of two or more NSAIDs is not recommended.
Warfarin: The concurrent use of non-steroidal anti-inflammatory drugs and warfarin has been associated with severe, sometimes fatal hemorrhage. Piroxicam should be used in combination with warfarin only if absolutely necessary and patients taking this combination of drugs should be closely monitored.
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.
Anti-hypertensives: There may be a reduction in the effect of anti-hypertensives.
Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycosides.
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 requirements of coumarin anticoagulants and other drugs that are highly protein bound when these are administered concomitantly with piroxicam. Such drugs include hydantoins, sulphonamides and sulfonylureas. Bleeding has been reported rarely when piroxicam, as well as other NSAIDs, have been administered to patients on coumarin type anticoagulants.
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.
Plasma lithium concentrations: NSAIDs including piroxicam have been shown to decrease the renal clearance and increase steady state plasma concentrations of lithium. Plasma lithium concentrations should be monitored when initiating, adjusting or discontinuing concurrent piroxicam.
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.
Quinolone antibiotics: Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
Mifepristone: In common with other NSAIDs, piroxicam should be avoided for at least 8 to 12 days following mifepristone administration as NSAIDs can reduce the effect of mifepristone.
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.

CONTRAINDICATIONS:
Piroxicam 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.
- 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.

ADVERSE REACTIONS:
Very common: Nausea, epigastric distress, abdominal pain and discomfort, flatulence, constipation and diarrhea. Other possible reactions are hypersensitivity signs, such as skin rash, headache, vertigo, asthenia, blood chemistry modifications, and increase in blood urea.
Less common: Vomiting, allergic oedema of the face and hands, blurred vision, tinnitus, aplastic anemia, leucopoenia, eosinophilia, pancytopenia, thrombocytopenia, increase in parameters of liver.functions, jaundice, acute renal insufficiency, water retention that may occur in the form of edema (mainly ankle edema), or cardiocirculatory disorders (hypertension, congestive heart failure). Sporadic cases of gastric ulcer with perforation, Stevens-Johnson's syndrome, Lyell's syndrome-, agranulocytosis, bladder disorders, shock and warning symptoms, acute heart failure. Stomatitis, alopecia and nail growth disorders have been reported.
Rare: Gastric ulcers and hemorrhages may also occur.

OVERDOSAGE:
In the event of overdosage with Piroxicam, supportive and symptomatic therapy is indicated. Studies indicate that administration of activated charcoal may result in reduced re-absorption of piroxicam, thus reducing the total amount of active drug available. Although there are no studies to date, haemodialysis is probably not useful in enhancing elimination of piroxicam since the drug is highly protein-bound.

INSTRUCTIONS:
- Store below 30ºC.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
PEXY Tablet 20 mg : Pack of 2 x 10 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

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