120x280mm

Hinocam

(Piroxicam)

Highnoon

COMPOSITION
Each tablet contains:
Piroxicam as Betacyclodextrin 20mg

DESCRIPTION
Hinocam (piroxicam) tablet is a nonsteroidal anti-inflammatory drug.

MECHANISM OF ACTION
Piroxicam has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action of piroxicam, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2). Piroxicam is a potent inhibitor of prostaglandin (PG) synthesis in vitro. Piroxicam concentrations reached during therapy have produced in vivo effects. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Prostaglandins are mediators of inflammation. Because piroxicam is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

PHARMACOKINETICS
Piroxicam is well absorbed from the gastrointestinal tract and peak plasma concentrations occur 3 to 5 hours after an oral dose. It is more rapidly absorbed after intramuscular use and is also absorbed to some degree after topical application. Piroxicam is 99% bound to plasma proteins. It has been detected in breast milk. Piroxicam has a long plasma elimination half-life of about 50 hours and steady-state concentrations are not reached 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 the feces. Enterohepatic recycling occurs. Less than 5% of the dose is excreted unchanged in the urine and feces. Piroxicam betadex dissociates in the gastrointestinal tract to its components piroxicam and betadex. Piroxicam absorption from piroxicam betadex is more rapid than that of unmodified piroxicam. Peak plasma concentrations of piroxicam occur 30 to 60 minutes after an oral dose. Betadex is not absorbed but is metabolized in the colon to various sugars.

INDICATIONS AND USAGE
It is indicated:
- For relief of the signs and symptoms of osteoarthritis
- For relief of the signs and symptoms of rheumatoid arthritis
- Pain relief in musculoskeletal conditions
- Children with juvenile idiopathic arthritis ages 6 years and over

DOSAGE AND ADMINISTRATION
Carefully consider the potential benefits and risks of Hinocam (piroxicam) and other treatment options before deciding to use Hinocam (piroxicam). Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.

After observing the response to initial therapy with Hinocam (piroxicam), the dose and frequency should be adjusted to suit an individual patient's needs. For the relief of rheumatoid arthritis and osteoarthritis, the dosage is 20 mg given orally once per day. If desired, the daily dose may be divided. Because of the long half-life of piroxicam, steady-state blood levels are not reached for 7 to 12 days. Therefore, although the therapeutic effects of piroxicam are evident early in treatment, there is a progressive increase in response over several weeks and the effect of therapy should not be assessed for two weeks.

The dosage in children ages 6 years and above for idiopathic juvenile arthritis the doses given according to the body weight;
- Less than 15 kg: 5 mg once daily
- 15 to 25 kg: 10 mg once daily
- 26 to 45 kg: 15 mg once daily
- 46 kg or over: 20 mg once daily

ADVERSE REACTIONS
The reported adverse events are; cardiovascular thrombotic events, GI bleeding, ulceration and perforation, hepatotoxicity, hypertension, heart failure and edema, serious skin reactions, renal toxicity and hyperkalemia, anaphylactic reactions, hematologic toxicity, anorexia, abdominal pain, constipation, diarrhea, flatulence, nausea, vomiting, dizziness, headache, vertigo, pruritus, rash, tinnitus, palpitations, stomatitis, drowsiness and blurred vision.

The additionally reported adverse events are fever, infection, sepsis, anaphylactic reactions, appetite changes, death, flu-like syndrome, pain (colic), serum sickness, congestive heart failure, hypertension, tachycardia, syncope, arrhythmia, exacerbation of angina, hypotension, myocardial infarction, vasculitis, dyspepsia, elevated liver enzymes, gross bleeding/perforation, heartburn, ulcers (gastric/duodenal), ulcerative colitis, dry mouth, esophagitis, gastritis, glossitis, hematemesis, hepatitis, jaundice, melena, rectal bleeding, eructation, liver failure, pancreatitis, anemia, increased bleeding time, ecchymosis, eosinophilia, epistaxis, leukopenia, purpura, petechial rash, aplastic anemia, thrombocytopenia, agranulocytosis, hemolytic anemia, lymphadenopathy, pancytopenia, positive ANA, weight changes, fluid retention, hyperglycemia, leucopenia, hypoglycemia, anxiety, asthenia, confusion, depression, dream abnormalities, insomnia, malaise, nervousness, paresthesia, somnolence, tremors, akathisia, convulsions, coma, hallucinations, meningitis, mood alterations, asthma, dyspnea, respiratory depression, pneumonia, alopecia, bruising, desquamation, erythema, photosensitivity, sweat, angioedema, toxic epidermal necrosis, erythema multiforme, exfoliative dermatitis, onycholysis, Stevens Johnson Syndrome, urticaria, vesiculobullous reaction, conjunctivitis, hearing impairment, swollen eyes, abnormal renal function, cystitis, dysuria, hematuria, hyperkalemia, interstitial, nephritis, nephrotic syndrome, oliguria/polyuria, proteinuria, renal failure, glomerulonephritis and decrease female fertility.

DRUG INTERACTIONS
- Piroxicam and anticoagulants such as warfarin have a synergistic effect on bleeding. The concomitant use of piroxicam and anticoagulants have an increased risk of serious bleeding compared to the use of either drug alone.
  - Serotonin release by platelets plays an important role in hemostasis. The concomitant use of drugs that interfere with serotonin reuptake and an NSAID may potentiate the risk of bleeding more than an NSAID alone. Monitor patients with concomitant use of piroxicam with anticoagulants (e.g., warfarin), antiplatelet drugs (e.g., aspirin), SSRIs, and SNRIs for signs of bleeding.
- The concomitant use of NSAIDs and analgesic doses of aspirin does not produce any greater therapeutic effect than the use of NSAIDs alone. The concomitant use of an NSAID and aspirin was associated with a significantly increased incidence of GI adverse reactions as compared to use of the NSAID alone. Concomitant use of piroxicam and analgesic doses of aspirin is not generally recommended because of the increased risk of bleeding.
- NSAIDs may diminish the antihypertensive effect of ACE inhibitors, ARBs, or beta-blockers (including propranolol).
  - In patients who are elderly, volume-depleted (including those on diuretic therapy), or have renal impairment, co-administration of an NSAID with ACE inhibitors or ARBs may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. During concomitant use of piroxicam and ACE inhibitors, ARBs, or beta-blockers, monitor blood pressure to ensure that the desired blood pressure is obtained.
  - During concomitant use of piroxicam and ACE inhibitors or ARBs in patients who are elderly, volume-depleted, or have impaired renal function, monitor for signs of worsening renal function.
  - When these drugs are administered concomitantly, patients should be adequately hydrated. Assess renal function at the beginning of the concomitant treatment and periodically thereafter.
- NSAIDs reduced the natriuretic effect of loop diuretics (e.g., furosemide) and thiazide diuretics in some patients. This effect has been attributed to the NSAID inhibition of renal prostaglandin synthesis. During concomitant use of piroxicam with diuretics, observe patients for signs of worsening renal function, in addition to assuring diuretic efficacy including antihypertensive effects.
- The concomitant use of piroxicam with digoxin has been reported to increase the serum concentration and prolong the half-life of digoxin. During concomitant use of piroxicam and digoxin, monitor serum digoxin levels.
- NSAIDs have produced elevations in plasma lithium levels and reductions in renal lithium clearance. During concomitant use of piroxicam and lithium, monitor patients for signs of lithium toxicity.
- Concomitant use of NSAIDs and methotrexate may increase the risk for methotrexate toxicity (e.g., neutropenia, thrombocytopenia, renal dysfunction). During concomitant use of piroxicam and methotrexate, monitor patients for methotrexate toxicity.
- Concomitant use of piroxicam and cyclosporine may increase cyclosporine's nephrotoxicity. During concomitant use of piroxicam and cyclosporine, monitor patients for signs of worsening renal function.
- Concomitant use of piroxicam with other NSAIDs or salicylates (e.g., diflunisal, salsalate) increases the risk of GI toxicity, with little or no increase in efficacy. The concomitant use of piroxicam with other NSAIDs or salicylates is not recommended.
- Concomitant use of piroxicam and pemetrexed may increase the risk of pemetrexed-associated myelosuppression, renal, and GI toxicity. During concomitant use of piroxicam and pemetrexed, in patients with renal impairment whose creatinine clearance ranges from 45 to 79 mL/min, monitor for myelosuppression, renal and GI toxicity. NSAIDs with short elimination half-lives (e.g., diclofenac, indomethacin) should be avoided for a period of two days before, the day of, and two days following administration of pemetrexed.
- Piroxicam is highly protein bound and, therefore, might be expected to displace other protein bound drugs. Physicians should closely monitor patients for a change in dosage requirements when administering piroxicam to patients on other highly protein bound drugs.
- Concomitant use of corticosteroids with piroxicam may increase the risk of GI ulceration or bleeding. Monitor patients with concomitant use of piroxicam with corticosteroids for signs of bleeding.

CONTRAINDICATIONS
It is contraindicated in the following patients:
- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to piroxicam or any components of the drug product History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients.
- In the setting of CABG surgery

WARNINGS AND PRECAUTIONS
- The reported data have shown an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction (MI), and stroke, which can be fatal. Based on available data, it is unclear that the risk for CV thrombotic events is similar for all NSAIDs. The relative increase in serious CV thrombotic events over baseline conferred by NSAID use appears to be similar in those with and without known CV disease or risk factors for CV disease. However, patients with known CV disease or risk factors had a higher absolute incidence of excess serious CV thrombotic events, due to their increased baseline rate. Some observational studies found that this increased risk of serious CV thrombotic events began as early as the first weeks of treatment. The increase in CV thrombotic risk has been observed most consistently at higher doses. To minimize the potential risk for an adverse CV event in NSAID-treated patients, use the lowest effective dose for the shortest duration possible. Physicians and patients should remain alert for the development of such events, throughout the entire treatment course, even in the absence of previous CV symptoms. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur. There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of aspirin and an NSAID, such as piroxicam, increases the risk of serious gastrointestinal (GI) events. A COX-2 selective NSAID for the treatment of pain in the first 10 to 14 days following CABG surgery found an increased incidence of myocardial infarction and stroke. NSAIDs are contraindicated in the setting of CABG.
  Avoid the use of piroxicam in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If piroxicam is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.
- NSAIDs, including piroxicam, cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. However, even short-term NSAID therapy is not without risk. Other factors that increase the risk of GI bleeding in patients treated with NSAIDs include longer duration of NSAID therapy; concomitant use of oral corticosteroids, antiplatelet drugs (such as aspirin), anticoagulants, or selective serotonin reuptake inhibitors (SSRIs), smoking, use of alcohol, older age, and poor general health status. Additionally, patients with advanced liver disease and/or coagulopathy are at increased risk for GI bleeding.

  Strategies to Minimize the GI Risks in NSAID-Treated Patients:
  - Use the lowest effective dosage for the shortest possible duration.
  - Avoid administration of more than one NSAID at a time.
  - Avoid use in patients at higher risk unless benefits are expected to outweigh the increased risk of bleeding. For such patients, as well as those with active GI bleeding, consider alternate therapies other than NSAIDs.
  - Remain alert for signs and symptoms of GI ulceration and bleeding during NSAID therapy.
  - If a serious GI adverse event is suspected, promptly initiate evaluation and treatment, and discontinue piroxicam until a serious GI adverse event is ruled out.
  - In the setting of concomitant use of low-dose aspirin for cardiac prophylaxis, monitor patients more closely for evidence of GI bleeding [see Drug Interactions (7)].
- Elevations of alanine aminotransferase (ALT) or aspartate aminotransferase (AST) have been reported. In addition, sometimes fatal, cases of severe hepatic injury, including fulminant hepatitis, liver necrosis, and hepatic failure have also been reported.

  Inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, diarrhea, pruritus, jaundice, right upper quadrant tenderness, and "flu-like" symptoms). If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash), discontinue piroxicam immediately, and perform a clinical evaluation of the patient.
- NSAIDs, including piroxicam, can lead to new onset of hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Patients taking angiotensin converting enzyme (ACE) inhibitors, thiazide diuretics, or loop diuretics may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure (BP) during the initiation of NSAID treatment and throughout the course of therapy.
- Fluid retention and edema have been observed in some patients treated with NSAIDs. Use of piroxicam may blunt the CV effects of several therapeutic agents used to treat these medical conditions (e.g., diuretics, ACE inhibitors, or angiotensin receptor blockers [ARBs]). Avoid the use of piroxicam in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If piroxicam is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.
- Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, dehydration, hypovolemia, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors or ARBs, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state. The renal effects of piroxicam may hasten the progression of renal dysfunction in patients with preexisting renal disease. Correct volume status in dehydrated or hypovolemic patients prior to initiating piroxicam. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia during use of piroxicam. Avoid the use of piroxicam in patients with advanced renal disease unless the benefits are expected to outweigh the risk of worsening renal function. If piroxicam is used in patients with advanced renal disease, monitor patients for signs of worsening renal function.
- NSAIDs, including piroxicam, can lead to new onset of hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Patients taking angiotensin converting enzyme (ACE) inhibitors, thiazide diuretics, or loop diuretics may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure (BP) during the initiation of NSAID treatment and throughout the course of therapy.
- Increases in serum potassium concentration, including hyperkalemia, have been reported with use of NSAIDs, even in some patients without renal impairment
- Piroxicam has been associated with anaphylactic reactions in patients with and without known hypersensitivity to piroxicam and in patients with aspirin-sensitive asthma.Seek emergency help if an anaphylactic reaction occurs.
- Patients with asthma may have aspirin-sensitive asthma which may include chronic rhinosinusitis complicated by nasal polyps; severe, potentially fatal bronchospasm; and/or intolerance to aspirin and other NSAIDs. Because cross-reactivity between aspirin and other NSAIDs has been reported in such aspirin-sensitive patients, piroxicam is contraindicated in patients with this form of aspirin sensitivity.
- NSAIDs, including piroxicam, can cause serious skin adverse reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Inform patients about the signs and symptoms of serious skin reactions, and to discontinue the use of piroxicam at the first appearance of skin rash or any other sign of hypersensitivity. Piroxicam is contraindicated in patients with previous serious skin reactions to NSAIDs.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as piroxicam. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia is often present. If such signs or symptoms are present, discontinue piroxicam and evaluate the patient immediately.
- Avoid use of NSAIDs, including piroxicam, in pregnant women at about 30 weeks gestation and later. NSAIDs, including piroxicam, increase the risk of premature closure of the fetal ductus arteriosus at approximately this gestational age.
- Use of NSAIDs, including piroxicam, at about 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Oligohydramnios is often, but not always, reversible with treatment discontinuation. Complications of prolonged oligohydramnios may, for example, include limb contractures and delayed lung maturation. Consider ultrasound monitoring of amniotic fluid if piroxicam treatment extends beyond 48 hours. Discontinue piroxicam if oligohydramnios occurs and follow up according to clinical practice.
- Anemia has occurred in NSAID-treated patients. This may be due to occult or gross blood loss, fluid retention, or an incompletely described effect on erythropoiesis. If a patient treated with piroxicam has any signs or symptoms of anemia, monitor hemoglobin or hematocrit. NSAIDs, including piroxicam, may increase the risk of bleeding events. Co-morbid conditions such as coagulation disorders, concomitant use of warfarin, other anticoagulants, antiplatelet drugs (e.g., aspirin), SSRIs, and serotonin norepinephrine reuptake inhibitors (SNRIs) may increase this risk. Monitor these patients for signs of bleeding.
- The pharmacological activity of piroxicam in reducing inflammation, and possibly fever, may diminish the utility of diagnostic signs in detecting infections.
- Because serious GI bleeding, hepatotoxicity, and renal injury can occur without warning symptoms or signs, consider monitoring patients on long-term NSAID treatment with a complete blood count (CBC) and a chemistry profile periodically.
- Because of reports of adverse eye findings with nonsteroidal anti-inflammatory agents, it is recommended that patients who develop visual complaints during treatment with piroxicam have ophthalmic evaluations.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
Use of NSAIDs, including piroxicam, can cause premature closure of the fetal ductus arteriosus and fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, limit dose and duration of piroxicam use between about 20 and 30 weeks of gestation, and avoid piroxicam use at about 30 weeks of gestation and later in pregnancy.

Lactation
Risk Summary
Limited data showed that the piroxicam is excreted in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for piroxicam and any potential adverse effects on the breastfed infant from the piroxicam or from the underlying maternal condition.

Females and Males of Reproductive Potential
Based on the mechanism of action, the use of prostaglandin-mediated NSAIDs, including piroxicam, may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women. Consider withdrawal of NSAIDs, including piroxicam, in women who have difficulties conceiving or who are undergoing investigation of infertility.

Pediatrics use
Piroxicam has not been investigated in pediatric patients. The safety and effectiveness of piroxicam have not been established.

Geriatric Use
Elderly patients, compared to younger patients, are at greater risk for NSAID-associated serious cardiovascular, gastrointestinal, and/or renal adverse reactions. If the anticipated benefit for the elderly patient outweighs these potential risks, start dosing at the low end of the dosing range, and monitor patients for adverse effects.

OVERDOSAGE
Symptoms following acute NSAID overdoses have been typically limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding has occurred. Hypertension, acute renal failure, respiratory depression, and coma have occurred, but were rare. Manage patients with symptomatic and supportive care following an acute NSAID overdose. There are no specific antidotes. If gastric decontamination may be potentially beneficial to the patient, e.g., short time since ingestion or a large overdosage (5 to 10 times the recommended dosage), consider emesis and/or activated charcoal (60 grams to 100 grams in adults, 1 gram to 2 grams per kg of body weight in pediatric patients) and/or an osmotic cathartic in symptomatic patients. The long plasma half-life of piroxicam should be considered when treating an overdose with piroxicam. Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

DOSAGE AND INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION
Hinocam 20mg Tablets: Alu. PVC. Blister Pack of 2 x 10's.

ہائینو کیم

(پائروکسی کیم)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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