Bosch

For Medical Professional only

BoshCam-B® 20mg Tablets
(Piroxicam-β-cyclodextrin)

بوش کیم ۔ بی ۲۰ ملی گرام ٹیبلیٹس
(پائروکسی کیم ۔ بیٹا ۔ سائیکلوڈیکسٹرین)

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.

COMPOSITION:
BoshCam-B 20mg Tablet
Each tablet contains:
Piroxicam U.S.P. 20mg
as Piroxicam Beta Cyclodextrin
(Product Specs.: Bosch)

CLINICAL PHARMACOLOGY:
Pharmacodynamic Properties:
Pharmacotherapeutic group: non-steroidal anti-inflammatory/anti-rheumatic drug. ATC code: M01AC01.

Mechanism of Action:
Piroxicam, belonging to the class of benzothiazine-based N-heterocyclic carboxyamides, is the first compound of a new class of NSAIDs, the oxicams. Piroxicam has an anti-inflammatory, analgesic and antipyretic activity, pharmacological actions similar to those of other non-steroidal anti-inflammatory drugs.

THERAPEUTIC INDICATIONS:
BoshCam-B (Piroxicam beta-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:
In rheumatic disorders a usual initial dose of **BoshCam-B** (Piroxicam beta-cyclodextrin) 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 2 days followed by 20mg daily for a total of 1 to 2 weeks. **BoshCam-B** (Piroxicam betacyclodextrin) is also used in acute gout, the usual dose being 40mg daily for 5 to 7 days. In the treatment of post operative pain following dental or minor surgery, the dose is 20mg daily. Higher doses of 40mg daily for the first 2 days are recommended following orthopaedic surgery. The dose may be reduced to 10mg daily in elderly patients.

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.

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.

WARNINGS AND PRECAUTIONS:

General

- 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. The rise in blood urea nitrogen as a rule is not 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. 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.

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 β-blocking agents is antagonized by NSAIDs.

Compromised Cardiac function:

Edema, mainly ankle edema, has been reported during piroxicam treatment; as with other nonsteroidal 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.

DRUG INTERACTIONS:

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.

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.

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.

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.

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.

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 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 EFFECTS:
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.

Uncommon:
Vomiting, allergic oedema of the face and hands, blurred vision, tinnitus, aplastic anaemia, 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

USE IN PREGNANCY AND LACTATION:
Pregnancy:
Piroxicam should not be used in pregnant women or those likely to become pregnant unless the expected benefits outweigh the potential risk.

Lactation:
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.

OVERDOSE:
In the event of overdose, appropriate supportive medical care should be provided.

SHELF LIFE:
2 years

STORAGE AND INSTRUCTION:
Protect from heat sunlight and moisture, store below 30°C.
Keep out of the reach of children.
The expiration date refer to the product correctly stored at the required condition.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.
" Product Contains Lactose"

PRESENTATION:
Boshcam-B: Cold Form & Cold Seal Pack of 20's Tablets

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: دھوپ، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دُور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

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