Brexin®

(Piroxicam-ß-cyclodextrin 191.2 mg)

BREXIN® is a new formulation of piroxicam as a complex with ß-cyclodextrin in the molar ratio 1 : 2.5.
ß-cyclodextrin, 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. BREXIN® is very soluble in water and has a more rapid and complete absorption than plain piroxicam after oral or rectal administration. The improved solubility leads to a rapid increase in plasma levels and peak value is reached earlier. In clinical terms this means a quicker and more intense analgesic and anti-inflammatory effect. The long half life of Brexin, which is the same as that of plain piroxicam, allows for just one single daily dose. Due to its pharmacodynamic and pharmacokinetic properties, BREXIN® is particularly suitable for the treatment of rheumatic and/or inflammatory disorders with painful symptoms that could seriously affect the general conditions and normal activity of patients and where a rapid and intense efficacy is required.

INDICATIONS:
Acute painful conditions.

PRESENTATION AND DOSAGE:
Tablets and sachets: 1 tablet or 1 sachet (equivalent to 20 mg of piroxicam) per day. Suppositories: one suppository (equivalent to 20 mg of piroxicam) per day. In elderly patients it may be necessary to reduce the dosage (half a tablet or half a sachet) and limit the duration of treatment.

CONTRAINDICATIONS:
Piroxicam must not be used in subjects known to be hypersensitive to the drug, nor in subjects with gastroduodenal ulcer, gastritis, dyspepsia, severe hepatic or renal disturbances, severe heart failure, severe hypertension, severe blood alterations or hemorrhagic diathesis. It is possible that cross sensitivity with acetylsalicylic acid or other NSAIDs exist. Therefore, piroxicam must not be administered to patients in whom acetylsalicylic acid or other NSAIDs induce the symptoms of asthma, rhinitis or urticaria. The product is contraindicated in ascertained or suspected pregnancy, during lactation and in children. The sachet form contains aspartame as a sweetener thus its use is inadvisable in patients with phenylketonuria.

PRECAUTIONS:
The product must be used under strict medical control in patients with a medical history of disturbances in the upper gastrointestinal tract. Particular caution must be taken in subjects with cardiocirculatory insufficiency, arterial hypertension, reduced hepatic or renal function, previous or current blood alterations, bronchial asthma and elderly patients. Piroxicam may affect concentration and it is therefore not advisable to drive or undertake any activity requiring quick reflex action. As with other drugs having similar activity, piroxicam may increase BUN in some patients; however, BUN does not keep on increasing as the therapy continues, but reaches a steady level which goes back to or towards the norm on discontinuing the treatment. The increase of BUN is not associated with an increase of serum creatinine. 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.

SIDE EFFECTS:
The most commonly found side effects are gastrointestinal disturbances which are represented by nausea, epigastric distress, constipation and diarrhoea. Other noted side effects: signs of hypersensitivity (skin rash), headache, vertigo, asthenia, changes in blood chemistry, increase of BUN. Rare side effects: gastric ulcers with or without hemorrhages, vomiting, allergic oedema of the face and hands, increase of cutaneous photosensitivity, ocular disturbances, aplastic anemia, pancytopenia, thrombocytopenia, increase of liver function parameters, jaundice, acute renal insufficiency, water retention that may occur in the form of oedema (mainly ankle oedema), or cardiocirculatory disturbances (hypertension, congestive heart failure). Sporadic cases of gastric ulcer with perforation, Stevens-Johnson syndrome, Lyell's disease, agranulocytosis, bladder disorders, shock and warning symptoms, acute heart failure, stomatitis, alopecia and nail growth disorders have been associated with the use of piroxicam.

OVERDOSAGE:
In the event of any overdosage with BREXIN® a supportive and symptomatic therapy should be given.

Use of sachets: by opening the sachet along the line marked "half dose" a 10 mg dose is obtained. By opening the sachet along the line marked "full dose" a 20 mg dose is obtained.
Suppositories: to be stored under +25°C.

PACKAGES:
Box of 20 scored tablets (20 mg)
Box of 20 double-pocket sachets (20 mg)
Box of 10 suppositories (20 mg)

KEEP OUT OF THE REACH OF CHILDREN

Chiesi

CHIESI FARMACEUTICI S.p.A. - 26/A, Via Palermo - PARMA - ITALY OFFICINE di PARMA

81H58/01

بریکسین گولیاں

پائروکسی کیم بیٹا سائیکلوڈیکسٹرین

اجزائے ترکیبی اور وضاحت:

بریکسین پائروکسی کیم اور بیٹا سائیکلوڈیکسٹرین کی نئی تشکیل ہے۔

بریکسین میں پائروکسی کیم اور بیٹا سائیکلوڈیکسٹرین 191.2 ملی گرام ہے جو کہ پائروکسی کیم 20 ملی گرام کے برابر ہے۔

علامات:

شدید درد کی حالت

خوراک:

ایک گولی دن میں ایک مرتبہ

ممانعت برائے علاج:

بریکسین ایسے کسی مریض کو نہیں دی جانی چاہئے جسے پائروکسی کیم سے ذودحسی (Hypersensitivity) ہو۔ معدے کا السر، معدے کی سوزش۔ جگر اور گردے کی شدید تکالیف، اور فشارِ خون کے مریضوں کو احتیاط سے استعمال کرائی جانی چاہیے، پائروکسی کیم کا استعمال ایسے مریضوں میں جنہیں ایسی ٹائل سیلی سائیکلک ایسڈ یا دوسرے این ایس اے آئی ڈیز (NSAID's) سے دمہ کی شکایت ہونے کا اندیشہ ہو، ناک کی سوزش اور جلدی خارش کی علامات ظاہر ہوتی ہوں۔ اسکے علاوہ جلد پر نشان پڑ جانا، سر درد، چکر آنا۔ بچوں اور حاملہ خواتین اور دودھ پلانے والی خواتین میں بریکسین ٹیبلٹ کی ممانعت ہے۔

منفی اور مضر اثرات:

عمومی طور پر مریضوں کو بریکسین ٹیبلٹ کے استعمال سے کوئی تکلیف نہیں ہوتی۔ البتہ کبھی کبھار مریض کو معدے کی تکلیف جیسے الٹی یا متلی، ہاضمہ کی خرابی، قبض، دست آنا وغیرہ میں سے کوئی ایک شکایت ہو جانا ممکن ہے۔

پیکنگ:

20 گولیوں کی ایک ڈبیہ۔

ہدایات:

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 30°C سے کم درجہ حرارت پر، نمی اور روشنی سے محفوظ رکھیں۔

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