Cyclodex

(Piroxicam β-cyclodextrin)

سائیکلوڈیکس

(پائروکزیکیم-بیٹا-سائیکلوڈیکسٹرین)

20mg Tablets

Composition
Each tablet contains:
Piroxicam-β-cyclodextrin
eq. to piroxicam ..... 20 mg
Product Complies Platinum Specs.

Cyclodex is a new formulation of piroxicam as a complex with β-cyclodextrin in the molar ratio 1: 2.5.

β-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. Cyclodex 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 Cyclodex, which is the same as that of plain piroxicam, allows for just one single daily dose. Due to its pharmacodynamic and pharmacokinetic properties, Cyclodex 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

DOSAGE AND ADMINISTRATION:

One tablet (equivalent to 20 mg of piroxicam) per day.

In elderly patients it may be necessary to reduce the dosage (half a tablet) 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.

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 an overdosage with Cyclodex a supportive and symptomatic therapy should be given.

STORAGE:

Store below 30°C in a dry place protect from light.

Keep out of the reach of children.

Dosage as directed by the physician.

To be dispensed on the prescription of a registered medical practitioner only.

PRESENTATION:

2 x 10's Tablets in Blister Pack

Note: Product contains lactose.

ہدایات:

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،

روشنی سے بچائیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔

بچوں کی پہنچ سے دُور رکھیں۔

Manufactured by:

Platinum Pharmaceuticals (Pvt) Ltd.

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Mfg. Lic No. 000415

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