

BETADEX

(Piroxicam-β-cyclodextrin)

20mg Tablets

COMPOSITION

Each tablet contains:
Piroxicam-β-cyclodextrin equivalent to Piroxicam 20mg

DESCRIPTION

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

MECHANISM OF ACTION

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. BETADEX 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 BETADEX, which is the same as that of plain piroxicam, allows for just one single daily dose. Due to its pharmacodynamic and pharmacokinetic properties, BETADEX is particularly suitable for the treatment of rheumatic and/or inflammatory disorders with painful symptoms that could seriously affect the general condition and normal activity of patients and where a rapid and intense efficacy is required.

INDICATIONS

Acute painful conditions, symptomatic relief of osteoarthritis, Rheumatoid Arthritis or Ankylosing Spondylitis.

DOSAGE AND ADMINISTRATION

Tablets: 1 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 neither 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 cardiorespiratory 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 normal 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.

POSSIBLE 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.

بیٹاڈیکس
(پایروکسیکام-بیٹا-سائیکلوڈیکسٹرین)
۲۰ ملی گرام گولیاں

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 BETADEX a supportive and symptomatic therapy should be given.

DRUG INTERACTIONS

Piroxicam shows interaction with following drugs:

Warfarin, protein bound drugs, methotrexate, aspirin & other NSAIDs, Plasma lithium concentrations, diuretics, Anti-hypertensive, cardiac glycoside, Quinolones, Mifepriston, cyclosporine, corticosteroids, aminoglycosides, oral hypoglycemic agents.

STORAGE CONDITIONS AND INSTRUCTIONS

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

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

• Keep out of the reach of children.

PRESENTATION

BETADEX 20 mg tablet available in blister pack of 20's tablets.

ہدایات:

- **خوراک:** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف ریزرو ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

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