

20-07-24
12-10-24

DOLBY 20mg TABLET Leaflet

Size: 76 x 178 inch

Dolby 20mg
(Piroxicam-β-cyclodextrin) Tablets

ڈولبی ۲۰
ٹیبلٹس
(پیروکسیم-β-سائیکلوڈیکسٹریں)

COMPOSITION:

Each tablet contains:
Piroxicam-β-cyclodextrin equivalent to Piroxicam 20mg
(Product complies innovator's specification)

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION:

Piroxicam an NSAID complex with cyclodextrin, possess analgesic and antipyretic properties, the complex allows single molecule of NSAID to be released adjacent to the gastrointestinal mucosa, instead of crystals. Since the time contact with gastric mucosa is reduced, the risk of direct contact gastric irritation is also reduced.

PHARMACOKINETICS:

Piroxicam beta-cyclodextrin dissociates in the gastrointestinal tract to piroxicam and betacyclodextrin. Piroxicam absorption from piroxicam beta-cyclodextrin is more rapid than that of unmodified piroxicam. Piroxicam is well absorbed from the gastrointestinal tract peak plasma concentrations of piroxicam are reached 30 to 60 minutes after an oral dose. beta-cyclodextrin is not absorbed but is metabolized in the colon to various sugars. Piroxicam is 99% bound to plasma proteins. Piroxicam has a long plasma elimination half life of about 50 hours. Because of this steady state conditions are not reached for 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 faeces. Enterohepatic recycling occurs. Less than 5% of the dose is excreted unchanged in the urine and faeces.

THERAPEUTIC INDICATIONS:

Piroxicam-beta-cyclodextrin is being used in the management of acute and chronic painful disorders like osteoarthritis, Rheumatoid arthritis, ankylosing spondylitis. Dysmenorrhea, toothache, migraine headache, post-operative and traumatic pain are also managed by this medicine.

DOSAGE & ADMINISTRATION:

In rheumatic disorders a usual initial dose of 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. 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-beta-cyclodextrin must not be used by patients with Active peptic ulcer, history of recurrent ulcerations, and Aspirin/anti-inflammatory induced allergy. It is contraindicated in conditions like Asthma, Pepticulcer, Thrombosis, Rhinitis, Urticaria, Impaired hepatic function, Angioedema, Hypersensitivity.

ADVERSE EFFECT:

Some patients may experience stomach disturbances, skin rash and reactions, oedema, Malaise, brain effects and Tinnitus (ringing in ears). Please consult your doctor if you experience any of these symptoms.

DRUG INTERACTION:

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. 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 hydantoin, sulphonamides and sulfonylureas. Bleeding has been reported rarely when piroxicam, as well as other NSAIDs,

have been administered to patients on coumarin type anticoagulants.

Extreme care should also be exercised in giving methotrexate to patients on piroxicam therapy, because lethal interactions have been reported between NSAIDs and methotrexate. 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. 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.

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. 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. There may be a reduction in the effect of anti-hypertensives.

NSAIDs may increase cyclosporine nephrotoxicity as a result of their effect on renal prostaglandins. There is increased risk of gastrointestinal bleeding with corticosteroids. Reduction in renal function in susceptible individuals, decreased elimination of aminoglycosides and increased plasma concentrations have been reported.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Piroxicam should be used with caution in patients with intrinsic coagulation defects and those on anticoagulant therapy. It should be used with caution in patients with compromised cardiac function, hypertension other condition predisposing to fluid retention.

Discontinue drug if skin reaction occurs. It should be used with extra care in the presence of existing controlled infection. Drug should not be given to Pregnant Mothers, patients suffering from Liver Malfunction, Geriatrics, and Neonates. If prescribing authority justifies the benefits of the drug against the possible damages he/she should reevaluate them and consult the reference material and previous studies.

PRESENTATIONS AVAILABLE

Dolby Tablet (Piroxicam beta-cyclodextrin) 20mg tablets are available in 2x10's Alu/Alu blister packed in Unit carton with leaflet.

INSTRUCTIONS:

- Store below 30°C.
- Keep all medicines out of reach of children.
- Protect from light, moisture, and heat.
- To be sold only on the prescription of a registered medical practitioner.

خود راک اور ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی، نمی اور گرمی سے بچائیں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر ہی فروخت کی جائے۔

Marketed by:
CENRJY
Pharmaceuticals

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