# Riacen®

## Piroxicam

**COMPOSITION**
Each capsule contains piroxicam B.P. 20 mg.

**PHARMACO-THERAPEUTICAL CLASSIFICATION**
Non-steroidal anti-inflammatory drug.

**INDICATIONS**
Treatment of pain and inflammation in rheumatic disease and other musculoskeletal disorders.

**CONTRAINDICATIONS**
Hypersensitivity to the product components. Piroxicam must not be used in the presences of peptic ulcers, gastritis, dyspepsia, severe liver and kidney disorder, severe cardiac insufficiency, severe hypertension, severe blood alterations, or in subjects with haemorrhagic diathesis. There is the possibility of reactions in subjects with known salicylate or NSAID hypersensitivity. The product must not be administered to patients in whom salicylate or other NSAIDs cause asthma, hayfever, nasal polyposis, Quinck's oedema or hives. The product should not be taken during pregnancy, breast feeding or childhood.

**PRECAUTIONS**
Patients with a history of disorders of the upper part of the gastrointestinal tract should only by administered the product under strict medical control. Particular care must also be taken when treating subjects with cardiocirculatory insufficiency, arterial hypertension, impaired liver and kidney function, renal hypoperfusion, previous or ongoing blood alterations, those undergoing diuretic therapy and elderly patients. In all these cases the clinical and laboratory parameters should be monitored regularly, especially in the case of prolonged treatment. As a result of interaction with the metabolism of arachidonic acid, in asthmatics and other sensitive subjects, the drug may cause bronchospasm attacks and even shock as well as other allergic phenomena. Like other substances with a similar action, increases in azotemia have been observed in some patients that do not go beyond a certain level with continued admanistration. Once treatment is suspended, the values return to normal. It is also advisable to control the blood sugar levels in diabetic patients and prothrombin time in subjects undergoing concomitant anticoagulant therapy with coumarin derivatives. The product, like other NSAIDs, reduces platelet aggregation and prolongs the coagulation time; this should be remembered when blood tests are carried out and requires particular care when the patient is already undergoing treatment with platelet aggregation inhibitors. As some ocular alterations have been recorded during treatment with NSAIDs, in the event of prolonged treatment, regular ophthalmic examinations are recommended.

**INTERACTIONS**
The product interacts with salicylates, with other NSAIDs and with substances that inhibit platelet aggregation. The concomitant administration of lithium and NSAIDs causes increases in the lithium concentration in plasma. Piroxicam binds strongly to protein and therefore will probably displace other protein-bound drugs. In the event of treatment with the product and other drugs which are highly protein bound the physician should monitor the patient and, if necessary, adjust the doses. Piroxicam absorption is slightly increased following the administration of cimetidine. This increase is not however clinically significant. Other possible interactions: piroxicam may reduce the efficacy of diuretics and, probably, antihypertensive drugs. When taken together with drugs containing potassium or diuretics, that determine potassium retention, there is a further danger of an increase in serum potassium concentrations (hyperpotassiemia). The contemporary administration of glucocorticoids may increase the danger of gastrointestinal haemorrhages. Not to be administered concurrently with salicylate or other NSAIDs. Alcohol should be avoided. Piroxicam can reduce the efficacy of intrauterine devices. NSAIDs should not be administered concurrently with quinolone drugs.

**SPECIAL PRECAUTIONS**
Piroxicam inhibits the synthesis and release of prostaglandins. This effect, as with other NSAIDs, has been associated with an increase in the frequency of dystocia and prolonged labour in pregnant animals to whom the drug was administered up to the final part of the pregnancy. The product may interfere with the state of awareness making it dangerous to drive or carry out operations that require particular vigilance and prompt reflexes.

**DOSAGE AND ADMINISTRATION**
ARTHROSIS, RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS. Initially 20 mg once daily. In some cases it may be appropriate to increase the dose to 30 mg/day in single or divided doses. In the majority of cases treatment may be continued with the dose of 20mg/day; in a limited number of patients a single administration of one 10 mg capsule may be sufficient.
ACUTE MUSCULOSKELETAL DISORDERS. For the first 2 days 40 mg daily in single or divided doses. If treatment is continued, the daily dose should be reduced to 20 mg.
GOUT. In the acute phase 40 mg as a single dose on the first day, then 40 mg daily in single or divided doses for 4-5 days. RIACEN® is not indicated for the chronic treatment of gout. Prolonged administration of doses higher than 30 mg/day increase the risk of gastrointestinal side effects. In the treatment of elderly patients, the dosage must be carefully determined by the physician, who can decide to reduce the above-mentioned doses, if necessary.

**OVERDOSE**
In the event of an overdose of RIACEN®, symptomatic treatment is indicated.

**SIDE EFFECTS**
The most commonly reported side effects are gastrointestinal, including nausea, indigestion, constipation, diarrhoea, flatulence, epigastric pain, anorexia. Occasional cases of gastric ulcer have been reported with and without haemorrhage, and perforations that were rarely fatal. Other (reported) side effects are: hypersensitive phenomena such as rashes, headache, dizziness, drowsiness, malaise, tinnitus, deafness, asthenia, blood alterations, decrease in haemoglobin and haematocrit, increase in azotaemia. Rarely there may be vomit, allergic oedema of the face and hands, increase in skin photosensitivity, sight disturbances, aplastic anaemia, haemolytic anaemia, pancytopenia, thrombocytopenia, Henoch-Schoenlein purpura, eosinophilia, increase in the liver functioning indices, jaundice with rare cases of fatal hepatitis. Therapy with piroxicam must be suspended if there are any signs or clinical symptoms of liver disorder. Rare cases have been reported of pancreatitis. There have been some cases of haematuria, dysuria, acute renal insufficiency, water retention, which may occur in the form of oedema especially in the lower legs or cardiocirculatory disorders (hypertension, heart failure). Sporadic cases have been reported of: epistaxis, haematemesis, melena, gastrointestinal bleeding, dry fauces, multiform erythema, ecchymosis, skin peeling, sweating, hypoglycemia, hyperglycemia, body weight variations, erethism, insomnia, depression, Stevens Johnson's syndrome, Lyell's syndrome, agranulocytosis, vesical dysfunction, shock and premonitory symptoms, acute heart failure, stomatitis, alopecia, nail growth disorders.

Please report to your physician or chemist any adverse effect not described in this leaflet.

**PACKAGING**
Box of 20 capsules.

**DO NOT USE THE DRUG AFTER THE EXPIRY DATE INDICATED ON THE PACKAGE. THIS DATE REFERS TO THE PRODUCT CORRECTLY STORED IN ITS UNOPENED PACKAGE. KEEP OUT OF THE REACH OF CHILDREN.**

Chiesi

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Manufactured by:
HIGHNOON LABORATORIES LTD.
17.5 K.M. Multan Road, Lahore-Pakistan.
under Licence of:
CHIESI FARMACEUTICI S.p.A., ITALY

# ریاسین کیپسول (پائروکسی کیم) ۲۰ ملی گرام

## اجزائے ترکیبی اور وضاحت:

ایک ریاسین کیپسول میں ۲۰ ملی گرام پائیروکسی کیم ہوتا ہے۔

## علامات:

عضلات، پٹھوں اور ہڈیوں کے جوڑوں کی درد اور سوجن،
ہڈیوں کی انحطاط پزیری سے منسلک جوڑوں کا مرض۔

## ممانعت برائے علاج:

ایسے مریض جن کو غیر اسٹرائیڈل ادویات بالخصوص پائیروکسی کیم سے الرجی ہو۔ معدے کا السر۔ معدے کی سوزش۔ معدے کی تیزابیت۔ جگر اور گردے کی شدید تکالیف کی صورت میں ریاسین کیپسول دوسری غیر اسٹرائیڈل ادویات کی طرح ممنوع ہیں۔ حاملہ یا دودھ پلانے والی خواتین میں بھی ریاسین کیپسول کی ممانعت ہے۔

## ترکیب استعمال:

ریاسین کیپسول کی عمومی خوراک ایک کیپسول ۲۰ ملی گرام روزانہ ہے۔ درد کی شدت زیادہ ہونے کی صورت میں پہلے دو دن ایک کیپسول ۲۰ ملی گرام صبح و شام اور پھر ایک کیپسول ۲۰ ملی گرام روزانہ۔

## منفی و مضر اثرات:

عام طور پر مریضوں کو ریاسین کیپسول کے استعمال سے کوئی تکلیف یا شکایت نہیں ہوتی۔ البتہ کبھی کبھار دوسری غیر اسٹرائیڈل ادویات کی طرح مریض کو معدہ کی تکالیف جیسے الٹی یا متلی، ہاضمہ کی خرابی، قبض وغیرہ میں سے کوئی ایک شکایت ہو جانا ممکن ہے۔ ایسی صورت میں اپنے معالج سے مشورہ کریں۔

## احتیاطی تدابیر:

دوا کو اپنے معالج کے مشورے سے استعمال کریں۔
دوا کو نمی، گرمی اور روشنی سے محفوظ رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

## پیشکش:

۲۰ کیپسول کی ایک ڈبیہ

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