

## CARLOS PIROXICAM CAPSULES USP 20 MG

### Composition:

Each capsule contains: Piroxicam BP 20 mg, Excipients q. s., Capsule shell contains approved colours

### Therapeutic Indications

Piroxicam is indicated for symptomatic relief of osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis.

Due to its safety profile, piroxicam is not a first line option should an NSAID be indicated. The decision to prescribe piroxicam should be based on an assessment of the individual patient's overall risks.

### Pharmacodynamic

Piroxicam is a non-steroidal anti-inflammatory agent which also possesses analgesic and antipyretic properties. Oedema, erythema, tissue proliferation, fever and pain can all be inhibited in laboratory animals by the administration of piroxicam. It is effective regardless of the aetiology of the inflammation. While its mode of action is not fully understood, independent studies *in vitro* as well as *in vivo* have shown that piroxicam interacts at several steps in the immune and inflammation responses through:

Inhibition of prostanoid synthesis, including prostaglandins, through a reversible inhibition of the cyclo-oxygenase enzyme.

### Pharmacokinetic

Piroxicam is well absorbed following oral or rectal administration. With food there is a slight delay in the rate but not the extent of absorption following administration. Drug plasma concentrations are proportional for 10 and 20mg doses and generally peak within 3 to 5 hours after medication. Piroxicam is extensively metabolized and less than 5% of the daily dose is excreted unchanged in urine and faeces.

### Posology and Method of Administration

The prescription of piroxicam should be initiated by physicians with experience in the diagnostic evaluation and treatment of patients with inflammatory or degenerative rheumatic diseases. The maximum recommended daily dose is 20mg.

**Elderly:** Elderly, frail or debilitated patients may tolerate side-effects less well and such patients should be carefully supervised. As with other NSAIDs, caution should be used in the treatment of elderly patients who are more likely to be suffering from impaired renal, hepatic or cardiac function.

### Contraindications

Hypersensitivity to the active substance or to any of the excipients.

- History of gastro-intestinal ulceration, bleeding or perforation.
- Patient history of gastrointestinal disorders that predispose to bleeding disorders such as ulcerative colitis, Crohn's disease, gastrointestinal cancers or diverticulitis.
- Patients with active peptic ulcer, inflammatory gastrointestinal disorder or gastrointestinal bleeding.
- Concomitant use with other NSAIDs, including COX-2 selective NSAIDs and acetylsalicylic acid at analgesic doses.
- Concomitant use with anticoagulants.
- History of previous serious allergic drug reaction of any type, especially cutaneous reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.
- Previous skin reaction (regardless of severity) to piroxicam, other NSAIDs and other medications.
- Patients in whom aspirin and other non-steroidal anti-inflammatory drugs induce the symptoms of asthma, nasal polyps, angioedema or urticaria.

## Special Warnings and Precautions for Use

Before taking piroxicam, tell your doctor or pharmacist if you are allergic to it; or to aspirin or other NSAIDs (such as ibuprofen, naproxen, celecoxib); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before taking this medication, tell your doctor or pharmacist your medical history, especially of: asthma (including a history of worsening breathing after taking aspirin or other NSAIDs), blood disorders (such as anemia, bleeding/clotting problems), growths in the nose (nasal polyps), heart disease (such as previous heart attack), high blood pressure, liver disease, stroke, throat/stomach/intestinal problems (such as bleeding, heartburn, ulcers)

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially stomach/intestinal bleeding and kidney problems.

## Interaction with other medicinal products and other forms of interaction

Products that may **interact** with this drug include: aliskiren, ACE inhibitors (such as captopril, lisinopril), angiotensin II receptor blockers (such as losartan, valsartan), cidofovir, corticosteroids (such as prednisone), lithium, "water pills" (diuretics such as furosemide).

## Fertility, pregnancy and lactation

**Pregnancy:** Although no teratogenic effects were seen in animal testing, the safety of Piroxicam during pregnancy or during lactation has not yet been established.

**Breast-feeding:** A study indicates that piroxicam appears in breast milk at about 1-3% of the maternal plasma concentrations.

**Fertility:** Based on the mechanism of action, the use of NSAIDs, including Piroxicam, may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women.

**Undesirable effects:** Upset stomach, heartburn, loss of appetite, stomach pain, nausea, vomiting; gas, diarrhea, constipation; dizziness, headache; itching, rash.

**Shelf-Life:** 3 years

**Storage:** Do not store above 30°C. Store in the original package.

**Nature and Contents of Container:** Blister strips formed from 25µm aluminum foil and 250µm thick opaque i.e. 10 x10 capsules

Manufactured and Marketed by:



**CARLOS PHARMACEUTICALS LIMITED,**

**Km 15, Goodluck Jonathan Bye-Pass,**

**Calabar, Cross River State, Nigeria.**