

SCHEDULED STATUS: S 3

PROPRIETARY NAME (AND  
DOSAGE FORM):

# Rheugesic Dispersible Tablets

## COMPOSITION

Each RHEUGESIC Dispersible Tablet  
contains : 20 mg piroxicam.

## PHARMACOLOGICAL CLASSIFICATION: PHARMACOLOGICAL ACTION

A3.1 Antirheumatics (anti-inflammatory agents). RHEUGESIC (piroxicam) is a non-steroidal anti-inflammatory agent which also possesses analgesic and antipyretic properties. Piroxicam inhibits the biosynthesis of prostaglandins.

RHEUGESIC (piroxicam) is completely absorbed following oral administration.

## INDICATIONS:

RHEUGESIC (piroxicam) is indicated for conditions requiring anti-inflammatory and/or analgesic activity, such as rheumatoid arthritis; osteo-arthritis; ankylosing spondylitis; acute musculoskeletal disorders, dysmenorrhea, postoperative pain and acute gout.

## CONTRA-INDICATIONS:

Piroxicam should not be used in patients with a history of gastro-intestinal haemorrhage, active peptic ulceration, aspirin sensitivity or hypersensitivity to piroxicam.

The safety of RHEUGESIC (piroxicam) use during pregnancy, lactation, porphyria and children under the age of 12 years has not yet been established.

collagen disease may be at increased risk of developing aseptic meningitis.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See 'Side-effects and Special Precautions'  
Treatment is supportive and symptomatic.

## IDENTIFICATION:

Round, white to yellow-white slightly curved tablet with breaking score on one side.

## PRESENTATION:

Packs of 10's, 30's and 100's in blister packs.

## STORAGE INSTRUCTIONS:

Store below 25°C in a dry place.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

## REGISTRATION NUMBER:

29/3.1/0302.

## NAME AND BUSINESS ADDRESS OF APPLICANT:

Cipla Medpro (Pty) Ltd.  
Rosen Heights, Pasita Street  
Rosen Park  
BELLVILLE 7530 RSA

## DATE OF PUBLICATION OF THIS PACKAGE INSERT:

April 1996

**Cipla Medpro**

## DOSAGE AND DIRECTIONS FOR USE

### **Rheumatoid arthritis; osteo-arthritis; ankylosing spondylitis**

The recommended starting dose is 20 mg given as a single daily dose. The majority of patients will be maintained on 20 mg daily. Some patients may require up to 30 mg daily given in single or divided doses.

### **Acute musculoskeletal disorders**

Therapy should be initiated with 40 mg daily for the first two days given in single or divided doses followed by 20 mg daily for 1 to 2 weeks.

### **Acute gout**

Therapy should be initiated by a single oral dose of 40 mg followed on then next 4 to 6 days by 40 mg given in a single or divided daily dosage **RHEUGESIC** (piroxicam) is not indicated for the long term management of gout.

### **Dysmenorrhoea:**

Treatment must be initiated at the earliest of symptoms with a recommended starting dose of 40 mg given as a daily dose for the first two days. Treatment may be continued thereafter with a single daily dose of 20 mg as necessary.

### **Directions for use:**

**RHEUGESIC** Dispersible Tablets form a rapid dispersion in water and may either be taken whole with fluid or dispersed in a minimum of 50 ml water and then swallowed.

### **SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

The most frequent adverse effects occurring with piroxicam are gastro-intestinal disturbance; reactions range from abdominal discomfort, nausea and vomiting, and abdominal pain to serious gastro- intestinal bleeding or activation of

peptic ulcer. Central nervous system-related side-effects include headache, dizziness, nervousness, tinnitus, depression, drowsiness, and insomnia. Hypersensitivity reactions may occur occasionally and include fever and rashes. Hepatotoxicity and aseptic meningitis which occur rarely may also be hypersensitivity reactions. Piroxicam can be also provoke bronchospasm in patients with asthma. Piroxicam may cause cystitis, haematuria, acute renal failure, interstitial nephritis, and nephrotic syndrome. Other adverse effects include anaemias, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis, abnormalities in liver functions tests, blurred vision, changes in visual colour perception, and toxic amblyopia.

### **Precautions:**

Piroxicam should not be given to patients with active peptic ulceration. It should be given with care to the elderly, to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, a history of peptic ulceration, and in liver or renal failure. Patients with congestive heart failure, cirrhosis, diuretic-induced volume depletion, or renal insufficiency require local synthesis of vasodilating prostaglandins to maintain renal perfusion, and therefore these patients are at greater risk of developing renal dysfunction due to NSAID-induced inhibition of renal prostaglandin synthesis. Care is required in those who are also receiving coumarin anticoagulants. Patients who are sensitive to aspirin or other NSAID's should generally not be given piroxicam. Piroxicam should be discontinued in patients who experience blurred or diminished vision or changes in colour vision. Patients with