PROFESSIONAL INFORMATION FOR

RHEUGESIC (DISPERSIBLE TABLETS)

SCHEDULING STATUS:

S2

PROPRIETARY NAME (and dosage form):

RHEUGESIC (Dispersible Tablets)

COMPOSITION:

Each **RHEUGESIC** Dispersible Tablet contains: 20 mg piroxicam.

The other ingredients are hydroxypropyl cellulose, lactose, magnesium stearate and microcrystalline cellulose.

PHARMACOLOGICAL CLASSIFICATION:

A 3.1 Antirheumatics (anti-inflammatory agents).

PHARMACOLOGICAL ACTION:

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 is indicated:

- For the emergency treatment of acute gout attacks.
- For the treatment of post-traumatic conditions (see **"DOSAGE AND DIRECTIONS FOR USE"**).

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.

DOSAGE AND DIRECTIONS FOR USE:

RHEUGESIC IS INDICATED FOR A MAXIMUM TREATMENT PERIOD OF 5 DAYS.

Use the lowest effective dose for the shortest possible duration of treatment.

Post-traumatic conditions

Take 20 mg (one tablet) daily for a maximum treatment period of 5 days.

Acute gout

Take 20 mg (one tablet) daily for a maximum treatment period of 5 days. **RHEUGESIC** (piroxicam) is not indicated for the long-term management of gout.

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.

PREGNANCY AND LACTATION:

The safety of **RHEUGESIC** use during pregnancy and lactation has not yet been established.

Regular use of non-steroidal anti-inflammatory drugs (NSAIDs) during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus *in utero* and possibly in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed, and its duration increased. (see "**CONTRAINDICATIONS**").

Use of NSAIDs, such as **RHEUGESIC**, around 20 weeks gestation or later in pregnancy may cause a rare but serious foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment.

Complications of prolonged oligohydramnios include limb contractures and delayed lung maturation, which may require invasive procedures such as exchange transfusion or dialysis, in some cases.

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. Hepatoxicity and aseptic meningitis which occur rarely may also be hypersensitivity reactions. Piroxicam can 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 function 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 collagen disease may be at increased risk of developing aseptic meningitis.

RHEUGESIC is contraindicated in pregnancy and lactation (see "**CONTRAINDICATIONS**").

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:

Outer carton containing a blister strip of 5 tablets.

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:

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