

## PROFESSIONAL INFORMATION FOR RHEUGESIC GEL

### SCHEDULING STATUS

S1

### 1 NAME OF THE MEDICINE

**RHEUGESIC GEL** (5 mg/g gel).

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of gel contains:

Piroxicam                    5 mg

Preservatives:

Benzyl alcohol            1,0 % *m/m*

Chlorocresol              0,12 % *m/m*

For full list of excipients see section **6.1**.

### 3 PHARMACEUTICAL FORM

Gel.

A clear yellow gel with a slight odour of menthol.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

RHEUGESIC GEL is indicated for:

The symptomatic treatment of musculoskeletal and joint disorders, such as

osteoarthritis of superficial joints, peri-arthritis, tendinitis, soft tissue disorders and acute musculoskeletal injuries.

## **4.2 Posology and method of administration**

### **Posology**

Apply 3 cm of gel to the affected area, three to four times daily.

Treatment should be reviewed after 2 weeks.

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

### **Method of administration**

RHEUGESIC GEL is for external use only.

## **4.3 Contraindications**

RHEUGESIC GEL is contraindicated in:

- Patients with hypersensitivity to piroxicam or to any of the excipients used in the formulation of RHEUGESIC GEL (see section **6.1**).
- Patients with hypersensitivity to anti-inflammatory agents or aspirin.
- Porphyria.
- Children.
- Pregnancy and lactation (see section **4.6**).

## **4.4 Special warnings and precautions for use**

- Life-threatening cutaneous reactions, including drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported with the use of systemic administration of piroxicam. These reactions have not been associated with topical piroxicam,

but the possibility of occurring with topical piroxicam, as in RHEUGESIC GEL, cannot be ruled out.

- Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of Stevens-Johnson syndrome or toxic epidermal necrolysis is within the first week of treatment.
- If signs or symptoms of Stevens-Johnson syndrome or toxic epidermal necrolysis (e.g., progressive skin rash often with blisters or mucosal lesions) are present, RHEUGESIC GEL treatment should be discontinued.
- The best results in managing Stevens-Johnson syndrome and toxic epidermal necrolysis come from early diagnosis and immediate discontinuation of any suspect medicine. Early withdrawal is associated with a better prognosis.
- If the patient has developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of piroxicam, RHEUGESIC GEL must not be re-started in this patient at any time.
- Cases of fixed drug eruption (FDE) have been reported with piroxicam. Piroxicam, as contained in RHEUGESIC GEL, should not be reintroduced in patients with history of piroxicam-related FDE. Potential cross reactivity might occur with other oxicams. Piroxicam should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
- Keep away from the eyes and mucosal surfaces. Do not apply to any sites affected by open skin lesions, dermatoses or infection.
- NSAIDs, including piroxicam, may cause interstitial nephritis, nephrotic syndrome and renal failure. There have also been reports of interstitial nephritis, nephrotic syndrome and renal failure with topical piroxicam, although the casual relationship to treatment with topical piroxicam, as contained in RHEUGESIC GEL, has not been established. As a result, the possibility that these events may be related to

the use of topical piroxicam cannot be ruled out.

#### **4.5 Interaction with other medicines and other forms of interaction**

None known.

#### **4.6 Fertility, pregnancy and lactation**

##### **Pregnancy**

RHEUGESIC GEL is contraindicated during pregnancy (see section **4.3**).

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 newborn. The onset of labour may be delayed and its duration increased (see section **4.3**).

Use of non-steroidal anti-inflammatory drugs (NSAIDs), such as RHEUGESIC GEL, 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.

##### **Breastfeeding**

RHEUGESIC GEL is contraindicated in breastfeeding (see section **4.3**).

Piroxicam, as contained in RHEUGESIC GEL, is distributed in breast milk and may also inhibit lactation.

## **Fertility**

Based on the mechanism of action, the use of NSAIDs, including piroxicam, may delay or prevent rupture of ovarian follicles, which have been associated with reversible infertility in some women. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of NSAIDs, including topical piroxicam, as contained in RHEUGESIC GEL, should be considered.

### **4.7 Effects on ability to drive and use machines**

RHEUGESIC GEL has no effect on the ability to drive and use machines.

### **4.8 Undesirable effects**

#### **Respiratory, thoracic and mediastinal disorders**

*Frequency unknown:*        Bronchospasm, dyspnoea.

#### **Gastrointestinal disorders**

*Less frequent:*                Nausea, dyspepsia, abdominal pain, gastritis.

#### **Skin and subcutaneous tissue disorders**

*Less frequent:*                Stevens-Johnson syndrome, toxic epidermal necrolysis.

*Frequency unknown:*        Fixed drug eruption, skin rash, phototoxic reactions, pemphigus vulgaris, contact dermatitis, eczema.

#### **Renal and urinary disorders**

*Less frequent:*                Nephrotic syndrome, interstitial nephritis.

#### **General disorders and administration site conditions**

*Frequency unknown:* Mild to moderate local irritation, erythema, pruritus.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> and to Cipla Medpro (Pty) Ltd., at [drugsafetysa@cipla.com](mailto:drugsafetysa@cipla.com) or telephone 080 222 6662 (toll free).

### **4.9 Overdose**

Overdosage is unlikely to occur with RHEUGESIC GEL.

However, in the case of overdose treatment is symptomatic and supportive.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

**Pharmacological classification:** A 3.1

**Pharmacotherapeutic group:** Antirheumatics (anti-inflammatory agent).

Piroxicam is a non-steroidal anti-inflammatory medicine useful in the treatment of inflammatory conditions. Although the mode of action for this agent is not precisely understood, piroxicam inhibits prostaglandin synthesis and release through reversible inhibition of the cyclo-oxygenase enzyme.

### **5.2 Pharmacokinetic properties**

*Absorption*

As a topical gel, piroxicam is absorbed to some degree.

### *Biotransformation*

Piroxicam is metabolised in the liver.

### *Elimination*

Piroxicam is excreted predominantly in the urine and in smaller amounts in the faeces. The elimination half-life is approximately 50 hours.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

- Benzyl alcohol
- Carbomer 980
- Chlorocresol
- Disodium edetate
- Glycerol
- Levomenthol
- Propylene glycol
- Purified water
- Triethanolamine.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

18 months.

#### **6.4 Special precautions for storage**

Store at or below 25 °C in a dry place.

Keep tube well closed.

#### **6.5 Nature and contents of the container**

RHEUGESIC GEL is packed in a 30 g, 40 g or 100 g collapsible aluminium tube with a white plastic cap. The tubes are packed in an outer cardboard carton.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal and other handling**

No special requirements.

### **7 HOLDER OF CERTIFICATE OF REGISTRATION**

#### **CIPLA MEDPRO (PTY) LTD.**

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

### **8 REGISTRATION NUMBER**

34/3.1/0141

### **9 DATE OF FIRST AUTHORISATION**

04 October 2001

**10 DATE OF REVISION OF THE TEXT**

23 May 2023

Namibia: NS1 04/3.1/1188