RHEUMAC®
DICLOFENAC SODIUM

COMPOSITION:

1. **RHEUMAC® 50; Each film coated tablet contains :** Diclofenac Sodium BP 50mg
2. **RHEUMAC® -EC : Each enteric coated tablets contains :** Diclofenac Sodium BP 50mg
3. **RHEUMAC® SR : Each sustained release tablets contain:** Diclofenac Sodium BP 50mg

INDICATIONS:

RHEUMAC® is used for the relief of pain and inflammation in:

- Rheumatoid Arthritis;
- Ankylosing Spondylitis;
- Osteoarthritis;
- Painful syndromes of the vertebral column;
- Non-articular rheumatism;
- Painful post-traumatic and post-operative inflammation and swelling;
- Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis.

DOSAGE:

The usual dose of **RHEUMAC®** (diclofenac sodium) by mouth is 75 to 150 mg daily in divided doses. The dose is best taken with a little milk or food to avoid a possible gastro-intestinal irritation.

RHEUMAC®SR tablets is administered as a single daily dose.

ADVERSE EFFECTS:

Those occurring occasionally:Epigastric pain; other gastro-intestinal symptoms such as nausea, vomiting, diarrhoea; abdominal cramps; dyspepsia; flatulence and anorexia.Headache, dizziness, and vertigo,skin rash,elevated serum aminotransferases (SGOT, SGPT).

Those occurring rarely:Gastro-intestinal bleeding; haematemesis; melena; peptic ulcer with or without bleeding or perforation; bloody diarrhoea.Tiredness (Lassitude).

urticaria, hepatitis with or without jaundice, hypersensitivity reactions such as asthma, systemic anaphylactoid reactions (including hypotension), oedema.

Those occurring in isolated cases:Lower gut disorders (e.g. non-specific haemmorhagic colitis and exacerbation of ulcerative colitis or Crohn's disease); aphthous stomatitis; glossitis; oesophageal lesions; constipation, sensory disturbances, including paraesthesia; memory disturbances; disorientation; disturbances of vision(blurred vision, diplopia); impaired hearing; tinnitus; insomnia; irritability; convulsions; depression; anxiety; nightmares; Stevens-Johnson Syndrome; Lyell's Syndrome; exfoliative dermatitis; loss of hair; photosensitivity reactions; purpura (including allergic purpura), fulminant hepatitis, palpitation; chest pain; hypertension.

CONTRAINDICATIONS, PRECAUTIONS, ETC.

Known hypersensitivity to diclofenac sodium; known allergy to aspirin or other non-steroidal anti-inflammatory drugs; and existing peptic ulcers; these would constitute definite contraindications to the use of **RHEUMAC®** in the patients concerned.

Caution in the case of elderly patients is necessary on fundamental medical grounds and it is advisable to employ the lowest effective dose for treating people who are frail or of low body weight.

Particular caution must be exercised in the case of patients with impaired cardiac or renal functions, or patients taking diuretics, or patients with extracellular volume depletion of any aetiology, e.g. before or after major surgery, in view of the importance of prostaglandins in maintaining renal blood flow.

When a prolonged treatment is undertaken with **RHEUMAC®**, periodic blood counts and monitoring of hepatic functions must be undertaken to forestall any harm which the treatment entails. Diclofenac Sodium can increase the activity of one or more of the liver enzymes.

RHEUMAC® (Diclofenac Sodium) may trigger off allergic, anaphylactic or anaphylactoid, reactions even if the patient is receiving the preparation for the first time.

Patients experiencing dizziness or other disturbances of the central nervous system during treatment with **RHEUMAC®** should not take charge of a vehicle or operate machinery.

INTERACTIONS:

Diclofenac may raise the plasma concentrations of lithium and digoxin if these are concurrently administered to the patient, necessitating their dose adjustments.

If an increase in the toxicity of methotrexate is to be avoided, the administrations of diclofenac and methotrexate must be spaced apart from each other by more than 24 hours. The bulk of clinical evidence, with the exception of some isolated cases, indicates that diclofenac does not interfere with the activity of anticoagulants. Nevertheless it would be in the patient's interest if he is monitored in this respect.

PHARMACOLOGY:

Pharmacodynamic Properties:

Diclofenac is the first of a series of phenylacetic acid derivatives developed as anti-inflammatory agents.

Diclofenac sodium is a therapeutic agent possessing analgesic, antipyretic and anti-inflammatory activities. It acts by inhibiting cyclo-oxygenase enzyme thereby inhibiting the biosynthesis of prostaglandins in the body which mediate in the pathogenesis of inflammation, fever and pain. Its potency to inhibit this enzyme is substantially greater than that of indomethacin, naproxen and several other agents.

In addition, diclofenac appears to reduce intracellular concentrations of free arachidonate in leucocytes, perhaps by altering the release or uptake of the fatty acid.

PHARMACOKINETICS PROPERTIES

Diclofenac is rapidly and completely absorbed after oral administration, however it is absorbed more slowly when given as an enteric coated tablet.

Diclofenac is also absorbed percutaneously.

Peak plasma concentrations in plasma are reached within 2 to 3 hours. Administration with food slows the rate, but does not alter the extent of absorption.

There is a substantial first-pass effect, such that only about 50% of Diclofenac is available systemically. The drug is extensively bound to plasma proteins (99%), and its half-life in plasma is 1 to 2 hours.

Diclofenac accumulates in synovial fluid after oral administration, which explains why the duration of therapeutic effect is considerably longer than the plasma half-life.

Diclofenac is metabolised in the liver to 4-hydroxydiclofenac, the principal metabolite, and other hydroxylated forms namely 5-hydroxydiclofenac, 3-hydroxydiclofenac and 4,5 dihydroxydiclofenac. After glucuronidation and sulfation, the metabolites are excreted in the urine (65%) and bile (35%).

LEGAL CATEGORY: Prescription Only Medicine. (POM)

THERAPEUTIC CATEGORY: ATC: M01A (Non steroidal Anti inflammatory and Anti rheumatic).

STORAGE CONDITION : Store in a dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

SHELF LIFE: As per product label.

PRESENTATION : Available in blister pack of 10 x 10's tablets and bulk pack of 1000's tablets

DATE OF LAST REVIEW : October 2017

LICENSE HOLDER : LABORATORY & ALLIED LTD.

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