Dicloneurobion Retard

Qualitative composition/Quantitative composition : Each extended release film coated tablet contains: Sodium Diclofenac 75 mg, Vitamin B1 (Thiamine HCl) 100 mg, Vitamin B6 (Pyridoxine HCl) 100 mg, Vitamin B12 (Cyanocobalamine 5 %) 1.0 mg, excipient q.s. 1 tablet.

Excipients.- Microcrystalline silicified cellulose, magnesium stearate, colloidal silicone dioxide, hydroxypropyl cellulose, hydroxypropyl metylcellulose, talc and opadry coral II.

Pharmaceutical form: Extended release film coated tablet

Pack of 20 tablets in blister pack of AL-AL.

Pharmacotherapeutic category: AINE, Antineuritic

Therapeutic indications: Anti-inflammatory with analgesic and antineuritic actions. Back pain, cervical pain, brachialgia, radiculitis, peripheral neuropathies caused by several etiologies, facial neuralgias, trigeminus neuralgia, intercostal neuralgia, herpetic neuralgia, alcoholic neuropathy, diabetic neuropathy, carpal tunnel syndrome, fibromyalgia, spondylitis.

Contraindications: Hypersensitivity to any of the formula ingredients. Polycytemia vera. Vitamin B12 should not be used in the early stages of Leber's disease (hereditary atrophy of the optic nerve). Gastroduodenal acid-peptic ulcer. In patients with bronchial asthma attacks, urticaria or acute rhinitis precipitated by acetylsalicylic acid or its derivatives.

Special warnings: Diclofenac may cause fluid retention, edema and clotting disorders. Administration of diclofenac alongside other NSAID's is not recommended. In dehydrated patients, the risk of renal toxicity increases. It should be administered cautiously in patients renal and hepatic disorders. Before drug product administration, digestive tract, liver and kidney status should be assessed.

Drug interactions and other forms of interaction: It has been reported that thiamine may increase the effect of neuromuscular blocking agents; its clinical significance is unknown. Pyridoxal phosphate reinforces peripheral decarboxylation of levodope and decreases its effectiveness in the treatment of Parkinson's disease. Concomitant administration of carbidope with levodope prevents this effect of pyridoxine. Pyridoxine hydrochloride should not be administered at doses above 5 mg/day to patients receiving levodope only. The administration of 200 mg/day of pyridoxine hydrochloride during one month may lead to a decrease up to 50% in serum concentrations of phenobarbital and phenytoine. Cycloserine and hydralazine are vitamin B6 antagonists and pyridoxine administration decreases neuronal side effects associated to the use of these compounds. Long-term use of penicilamine may cause vitamin B6 deficiency. When pyridoxine and cyclosporine are administered concomitantly, plasma concentrations of the latter agent may decrease.
Vitamin B12 absorption in gastrointestinal system may be reduced by the administration of the following drugs: aminoglycosides, colchicine, agents based on extended-release potassium, aminosalicylic acid and its salts, anticonvulsive agents (phenytoine, phenobarbital, primidone), cobalt radiation in the small intestine and by excessive intake of alcohol for more than 2 weeks. Concomitant administration of neomycin and colchicine increases vitamin B12 malabsorption. Ascorbic acid may destroy important amounts of vitamin B12 and of the intrinsic factor *in vitro*, thus, this possibility should be considered when administering high doses of ascorbic acid concomitantly with vitamin B12 by oral route. It has been reported that prednisone increases vitamin B12 absorption and intrinsic factor secretion in some patients with pernicious anemia, but not in patients with partial or total gastrectomy. Clinical significance of these observations is

unknown. Concomitant administration of chloramphenicol and vitaminB12 may affect the hematopoietic response to vitamin.
Simultaneous administration of diclofenac with agents based on lithium or digoxin or with potassium-sparing diuretics may increase plasma concentrations of these drugs. It is recommended to carry out an appropriate pharmacosurveillance. The concomitant use with other non-steroidal anti-inflammatory drugs may increase the risk of adverse side effects. Close monitoring should be exercised in patients treated with anticoagulant agents. Non-steroidal anti-inflammatory drugs should be discontinued 24 hours before the administration of methotrexate in order to avoid increased plasma concentrations of the cytostatic agent and its toxic effects.

Precautions for use: Before prescribing this product, the condition of the digestive system, liver and kidneys should be investigated.

Pregnancy and Breast feeding: The product must not be used during pregnancy and lactation.

Effect on ability to drive and to use machines: There is not effect on the ability to drive and/or to use machines with the use of diclofenac and B vitamins reported to date.

Intake or use of other medications: Inform your physician or pharmacist if you are taking another drug.

Dosage: In adults, daily dose is 100 mg, both for long-term and short-term treatment. The dose may be increased up to 200 mg/day in cases of exacerbation of chronic inflammatory processes

Method and route of administration: oral

Frequency and the time at which the drug should be taken:

Duration of the treatment: Patients may be treated for long periods if this is considered necessary by their physician.

Undesirable effects: Abdominal pain, nausea, vomit, diarrhea, dyspepsia, flatulence, anorexia; rarely: gastroduodenal bleeding, melena, hematemesis, ulcer perforation, bloody diarrhea. Occasionally: ulcerative colitis or Crohn's disease, gingivostomatitis, esophageal injuries, glossitis, constipation. Vertigo, confusion, headache, fatigue. Rare: paresthesia, sensitivity and visual disorders, memory disorders, disorientation, tinnitus, insomnia, psychotic irritations, taste disorders. Isolated cases of vesicular rash, eczema, multiform erythema, Steven-Johnson's syndrome, Lyell's syndrome, erythrodermia (exfolliative dermatitis), alopecia, photosensitivity reactions, purpura. Rarely hematuria, proteinuria, acute renal failure. Rarely hepatitis with or without jaundice. Isolated cases of thrombocytopenia, leukopenia, hemolytic anemia, aplastic anemia, agranulocytosis. Rarely hypotension, edema, anaphylactic reactions.

REPORT ANY UNDESIRABLE OR DISTRESSING EFFECT WHICH HAS NOT BEEN MENTIONED IN THE PACKAGE INSERT TO YOUR PHYSICIAN OR YOUR PHARMACIST.

Storage: store below 30°C in a dry place.

KEEP OUT OF THE REACH OF CHILDREN