Diclo-Neurobion®

DESCRIPTION Film coated tablets of Diclofenac sodium and vitamins B1, B6, and B12. Each film -coated tablet contains: Diclofenac sodium 50.00 mg, Vitamin B1 (Thiamine mononitrate) 50 mg, Vitamin B6 (Pyridoxine HCl) 50 mg, Vitamin B12 (Cyanocobalamin) 1 mg, Excipient q.s. 1 tablet.

INDICATIONS Analgesic, antineuritic, and antiinflammatory. Back pain, neck pain, arm pain, radiculitis, peripheral neuropathy of diverse etiology, facial neuralgias, trigeminal neuralgia, intercostal neuralgia, herpetic neuralgia, alcoholic neuropathy, diabetic neuropathy, carpal tunnel syndrome, fibromyalgia, spondylitis.

CONTRAINDICATIONS Hypersensitivity to any of the constituents of the product. Polycythemia vera. Vitamin B12 must not be used in the early stages of Leber's disease (hereditary atrophy of the optic nerve). Gastroduodenal/peptic ulcer. Patients in whom episodes of bronchial asthma, urticaria or rhinitis are triggered by acetylsalicylic acid or its derivatives.

PRECAUTIONS Diclofenac can cause fluid retention, edema, and coagulation disturbances in patients with cardiovascular disease.

Administration of diclofenac alongside other NSAIDs is not recommended.

In patients with dehydration, there is an increased risk of renal toxicity.

The product should be used with caution in patients with kidney or liver disturbances. Before prescribing this product, the condition of the digestive system, liver, and kidneys should be investigated.

Pregnancy & lactation The product must not be used during pregnancy or lactation.

SIDE EFFECTS They include: GI disturbances, dizziness, headache, and other central nervous system disturbances, isolated cases of skin eruptions, rare cases of hematuria, proteinuria, rare cases of liver function disturbances, isolated cases of thrombocytopenia, leukopenia, anemia, agranulocytosis, and rare severe hypersensitivity reactions.

DRUG INTERACTIONS AND OTHER FORMS OF INTERACTION Pyridoxine hydrochloride must not be given at doses higher than 5 mg per day to patients being treated with levodopa alone. Treatment with 200 mg pyridoxine hydrochloride per day for one month produces decreases of up to 50% in serum concentrations of phenobarbital and phenytoin. If pyridoxine is given alongside cyclosporin, plasma concentrations of the latter may be reduced. The absorption of vitamin B12 in the gastrointestinal system may be reduced by administration of the following: aminoglycosides, colchicine, prolonged-release potassium-based products, aminosalicylic acid and its salts, anticonvulsants (phenytoin, phenobarbital, primidone), irritation of the small intestine by cobalt, and by excessive alcohol intake for periods of more than two weeks. The simultaneous administration of neomycin and colchicine aggravates poor absorption of vitamin B12. The simultaneous administration of chloramphenicol and vitamin B12 can antagonize the hemopoietic response to the vitamin. The simultaneous administration of diclofenac with lithium-based products or digoxin or with potassium-sparing diuretics can cause plasma elevations of these drugs. Appropriate monitoring is recommended in such cases. The concomitant use of other nonsteroidal antiinflammatories can increase the risk of undesirable side effects. Patients treated with anticoagulants should be closely monitored. Nonsteroidal antiinflammatories should be discontinued 24 hours before initiating treatment with methotrexate so as to avoid plasma elevations of the cytostatic and the occurrence of toxic effects.

DOSAGE & ADMINISTRATION Three film coated tablets per day, to be taken orally preferably after food. Patients may be treated for long periods if this is considered necessary by their doctor.

PRESENTATION Box of 20 coated tablets

Reg. N° Lebanon 0024345

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