DEXABION®

Injectable Solution

Qualitative composition/Quantitative composition: Each amber ampoule (I) of 1 mL contains: Vitamin B1 (Thiamine HCl) 100 mg, Vitamin B6 (Pyridoxine HCl) 100 mg, Vehicle q.s. 1 mL ; Each amber ampoule (II) of 2 mL contains: Sodium Phosphate of dexamethasone eq to 4 mg of Dexamethasone phosphate, Vitamin B12 (Cyanocobalamin) 5.0 mg, Lidocaine HCl 30 mg Vehicle q.s. 2 mL.
Excipients.- Ampoule (I) 1 mL: Benzyl alcohol, sodium hydroxide and water for injection. Ampoule (II) of 2 mL: potassium cyanide, citric acid hydrated, sodium phosphate dibasic dehydrated and water for injection
Pharmaceutical form: Injection solution
Pack of three ampoules of 2 mL, and three of 1 mL with syringe.
Pharmacotherapeutic category: Steroid Anti-inflammatory, Antineuritic
Therapeutic indications:
Neurology: Neuritis, neuralgias, intercostal neuralgia, sciatica, facial paresis, radiculoneuritis, cervical syndrome, intervertebral disc herniation, myalgia, lumbago, tendonitis, scapula – humeral syndrome. Orthopaedics and Traumatology: Pre and post surgical trauma, initial treatment of acute neuritis and the joint or extra joint rheumatism, which the inflammation must be decreased rapidly.
Contraindications: Hypersensitivity to any of the constituents of the product formula. Vitamin B12 must not be used in the early stages of Leber's disease (hereditary atrophy of the optic nerve). Gastro duodenal ulcer, fungi generalized infections, viral infections (varicella, herpes zoster), tuberculosis, and glaucoma.
Special warnings. Thiamine: History of allergies to the preparations containing thiamine.

Pyridoxine. Neonatal seizures, simultaneous treatment with levodopa.

Cyanocobalamin. Cyanocobalamin treatment may mask folic acid deficiency. High amounts of folic acid may correct megaloblastosis caused by vitamin B12 deficiency, but do not prevent neurological complications, which may be irreversible.

Dexamethasone: It may increase sodium retention risk, potassium loss and oedema in patients with congestive heart failure, renal failure, and hypertension. Hypothyroidism and hepatic cirrhosis may increase corticosteroid effects. Corticosteroids may mask signs of infection. It should be used with caution in patients with osteoporosis. Psychotic patients may present fluctuations in symptoms during treatment.

Drug interactions and other forms of interaction: Concomitant use of glucocorticoids with diuretics and/or cardiac glycosides, hypoglycaemic agents, non-steroidal anti-inflammatory drugs, oral anticoagulant agents, and active vaccines may induce clinically significant interactions.
Glucocorticoids may be less efficacious when concomitantly used with hepatic enzyme inducers as: rifampin, ephedrine, barbiturates, phenytoin, and primidone.

It has been informed that thiamine may increase the effect of neuromuscular blocker agents. The clinical significance of this is unknown.

Pyridoxal phosphate reinforces peripheral decarboxylation of levodopa and decreases its efficacy in the treatment of Parkinson's disease. Concomitant treatment of carbidopa with levodopa prevents pyridoxine effect. Pyridoxine hydrochloride should not be administered at doses above 5 mg/day to patients receiving levodopa alone. Cycloserine and hydralazine are vitamin B6 antagonists and pyridoxine administration decreases neuronal side effects associated to the use of these compounds. When pyridoxine and cyclosporine are simultaneously administered, plasma concentrations of the latter one may be reduced.

Vitamin B12 absorption in the gastrointestinal system may be reduced due to the administration of the following drugs: aminoglycosides, colchicine, long-acting potassium preparations, aminosalicylic acid and its salts, anticonvulsive agents (phenytoin, phenobarbital, primidone), and an excessive alcohol intake for more than two weeks. It has been informed that prednisone increases vitamin B12 absorption and intrinsic factor absorption in some patients with pernicious anaemia, but not in patients with partial or total gastrectomy. The clinical significance of these observations is unknown. Concomitant administration of chloramphenicol and vitamin B12 may antagonize the haematopoietic response of the vitamin.
Pregnancy and Breast feeding: The product must not be used during pregnancy and lactation.
Intake or use of other medications: Inform your physician or pharmacist if you are taking another drug.
Dosage: Mix the contents of vials number I and number II.
Administrate by deep intramuscular injection, every 24 hours, for five days.

Undesirable effects: Occasionally, heart arrhythmias, gastric and/or duodenal ulcer, insomnia, irritability, nervousness, euphoria, psychosis, vomit, hyperthyroidism, hyperglycaemia, intraocular pressure increase, muscle weakness, skin hypersensitivity reactions, and rarely, anaphylactic shock in susceptible persons, adrenal suppression, and Cushing's syndrome may occur.

REPORT ANY UNDESIRABLE OR DISTRESSING EFFECT WHICH HAS NOT BEEN MENTIONED IN THE PACKAGE INSERTTO YOUR PHYSICIAN OR YOUR PHARMACIST.
OVERDOSE OR ACCIDENTAL INTAKE. MANIFESTATIONS AND MANAGEMENT (ANTIDOTES). Although pyridoxine has been considered relatively as non toxic, at the long term (i.e. two months or more) and in mega doses (i.e. usually 2 grams or more a day), pyridoxine may cause sensory neuropathy or neuropathic syndromes. Upon pyridoxine discontinuation, neurological impairment gradually improves until patient's recovery.

HOW SUPPLIED
Box with three 1-mL number I ampoule, and three 2-mL number II ampoule.
Storage: store below 30°C, protect against the light.
KEEP OUT OF THE REACH OF CHILDREN

Reg. Nº Lebanon 167484/10

Packed by **Pharmaline** - Lebanon,
Licensed by **Merck S.A de C.V., a subsidiary of Merck KgAa** - Germany

Rev. 06/2011 905086-A