DIFEN® B12

DICLOFENAC SODIUM 75 mg
BETAMETHASONE (as DISODIUM PHOSPHATE) 2 mg
HYDROXOCOBALAMIN (as SULPHATE) 10 mg
INJECTION I.M.
Rx only
Made in Argentina

PATIENT INFORMATION
- CONSULT YOUR DOCTOR -

Read this patient information before initiating DIFEN B12 and every time you repeat the recipe as there may be new information. This information does not replace your conversation with your doctor about your illness or treatment.

What is DIFEN B12 and what is it used for? Active ingredients of DIFEN B12 are diclofenac sodium, a drug that belongs to the group of nonsteroidal anti-inflammatory drugs (NSAIDs), betamethasone, a corticoid and hydroxocobalamin (B12 vitamin). DIFEN B12 is a medicine to relieve pain and inflammation and promote nerve regeneration, which is used for the treatment of acute musculoskeletal conditions (of bones, joints and muscles) as low back pain (back pain), lumbociatalgia, and episodes of worsening of chronic rheumatic disorders such as rheumatoid arthritis, osteoarthritis (arthrosis), ankylosing spondylitis (a form of arthritis that affects the joints of the spine) and gout.

Before using DIFEN B12
It is important that you use the lowest dose that would alleviate / control the pain and do not use this medication more time than necessary to control your symptoms.

Do not use DIFEN B12 If

- If you are allergic / hypersensitive to diclofenac, betamethasone and other corticosteroids, vitamin B12 or any of the other components of this product.
- If you are allergic to aspirin or other similar analgesics. Reactions can include trouble breathing, urticaria, nasal congestion or swelling of the face.
- If you had a hemorrhage or perforation of the stomach or intestine.

Pregnancy and lactation
DIFEN B12 should not be used during the first and second trimester of pregnancy unless your doctor considers strictly necessary. DIFEN B12 should not be administered during the third trimester of pregnancy because it may cause serious cardiovascular alteration in the fetus, with potential fetal death.
It is not recommended the use of DIFEN B12 if you are breast-feeding.

Driving and using machines
At normal doses, DIFEN B12, does not affect the ability to drive or use machines. However, if you experience drowsiness, vertigo, dizziness or impaired vision avoid driving and handling machinery.

How to use DIFEN B12?
Follow exactly the administration instructions provided by your doctor. Do not apply DIFEN B12 in doses higher nor longer than indicated by the doctor.
Administer one to two ampoules per day, exclusively by deep intramuscular route, (e.g. in the superoexternal quadrant of the gluteal region), slowly.
The maximum dose is 2 ampoules per day.
DIFEN B12 administration for a period of more than 3 days without a new medical indication is not recommended.
Is not recommended the use of DIFEN B12 in patients under 12 years of age.

Appropriate use of DIFEN B12
If you forgot to take DIFEN B12
Do not apply a double dose to compensate the missed dose. If you miss a dose, apply it as soon possible, unless it is almost time for the next; then back to the regular guideline. If you forget several doses, check with your doctor.

Undesirable effects (adverse)
Like all medicines, DIFEN B12 can produce adverse effects in some people.
The following adverse events have been reported during treatment with the components of the product, it does not imply that all of them are causally related to the same.
-Diclofenac
Incidence greater than 1% of treated cases. Probable causal relationship.
General: abdominal pain or cramps, headaches, fluid retention, abdominal distension.
Digestive system: diarrhea, digestive disorders, nausea, constipation, flatulence, alterations of liver lab tests, peptic ulcer with or without bleeding and perforation or hemorrhage without ulcer.
Nervous system: vertigo.
Skin and appendages: rashes, itching.
Special senses: tinnitus.
Incidence (Less than 1% of treated cases): general discomfort, allergic type reactions, hypertension, congestive heart failure, vomiting, jaundice, melena, aphthous stomatitis, dry mouth and mucous, bloody diarrhea, hepatitis, pancreatitis with or without concomitant hepatitis, decreased hemoglobin, leukopenia, thrombocytopenia, purpura, high levels of urea, insomnia, depression, fatigue, double vision, anxiety, irritability, epistaxis, asthma, laryngeal edema, alopecia, urticaria, eczema, dermatitis, angioedema, blurred vision, changes in taste, reversible loss of hearing, scotomas, proteinuria.
-Betamethasone
Betamethasone, used at the recommended doses for short periods of time (not more than two weeks) is generally well tolerated. The following adverse effects are often seen with high doses or prolonged treatments.
Hydroelectrolytic disorders: sodium retention, fluid retention, congestive heart failure in susceptible patients, decreased blood potassium, hypertension.
Musculoskeletal: muscle weakness, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of humerus and femur head, pathological fractures of long bones.
Gastrointestinal: peptic ulcer with or without perforation or hemorrhage, pancreatitis, abdominal distention, ulcerative esophagitis.
Dermatologics: alteration of healing of wounds, thin and fragile skin, ecchymoses and petechiae, facial erythema, increased sweating, can turn negative the skin reaction tests.
Neurological: seizures, increased intracranial pressure with edema of papilla, vertigo, headache.
Endocrine: menstrual irregularities, Cushing's syndrome, suppression of growth in children, lack of response of adrenal and pituitary, particularly in situations of stress (trauma, surgery, etc.), decreased carbohydrate tolerance, increased requirements for insulin or oral hypoglycemic in patients with diabetes mellitus, or subclinical diabetes mellitus onset.
Ophtalmological: cataracts (posterior subcapsular), increased intraocular pressure, glaucoma, exophthalmos (bulging eyes).
Metabolic: protein catabolism (protein degradation).
With parenteral administration have been noted in addition: hyperpigmentation or hypopigmentation, cutaneous and subcutaneous atrophy, sterile abscesses.

- If you suffer from a serious disease of the kidney or liver, asthma, bleeding disorders, hepatic porphyria or severe heart failure.
- If you are pregnant.
- If you suffer from bleeding disorders
- If they have cardiovascular problems, history of stroke or risk of suffer these conditions (for example, if you have high blood pressure or high cholesterol, diabetes, or if you smoke).
- If you have infections, especially systemic fungal infections (by fungi), infections by viruses, particularly herpes, chickenpox or measles, tuberculosis or positive reaction to tuberculin (Mantoux reaction), Strongyloides (strongyloidiasis) infestation, or if it has been recently vaccinated.
- If you have ulcerative colitis, diverticulitis, recent intestinal anastomosis, myasthenia gravis, osteoporosis, diabetes, glaucoma (ocular pressure) or a family history of glaucoma, a history of myopathy induced by corticosteroids or epilepsy.
- If you suffer from emotional instability or psychotic tendencies.

Take special care with DIFEN B12
DIFEN B12 should not be administered intravenously.
DIFEN B12, like all medicines containing non-steroidal anti-inflammatory drugs, should be used at the lowest possible effective dose and for the shortest time possible to control symptoms.
Prolonged corticoid treatment interruption should not abruptly, but reducing the dose gradually.
Treatment with DIFEN B12 can mask some signs of infection (e.g., fever). Prolonged use of corticosteroids may produce decreased resistance to infections and the ability for its location.
Patients in treatment with corticosteroids, especially in high doses, should not be vaccinated, because of the possibility of neurological complications and decrease in the immune response.
Measles and chickenpox may have a more severe evolution, even fatal, in individuals treated with corticosteroids.
In the same way, corticosteroids should be used with extreme caution in patients with known or suspected Strongyloides parasite infestation.
DIFEN B12 use in patients with active tuberculosis should be avoided. Use in individuals with latent tuberculosis or positive reaction to the PPD requires close observation, because a reactivation of the disease may occur.
There have been reports of low blood potassium with risk of cardiac arrhythmias when starting treatment with hydroxocobalamin, so the serum potassium concentration should be controlled. Consult with your doctor if you experience nausea, fatigue or flu-like symptoms, yellowing of skin and eyes, or pain in the upper part of the abdomen, that could be a liver problem associated or not with the administration of the medication. Also immediately consult with your doctor if you have severe or persistent abdominal pain or black stools or vomiting with blood.
The non-steroidal anti-inflammatory such as diclofenac may be associated with an increased risk of myocardial infarction or stroke, especially when used at high doses and prolonged treatments. Do not exceed the dose or the duration of the recommended treatment. Also, this type of medication can cause fluid retention, especially in patients with heart failure or high blood pressure.
DIFEN B12 should not be used during the postoperative period of coronary artery bypass surgery.

Taking other medicines simultaneously
Tell your doctor if you are taking or have recently taken any other medications, including those acquired without a prescription.
Certain medicines may interact with DIFEN B12; in these cases may be necessary to change the dose or stop treatment with any of them.
It is important to inform your doctor especially if you are taking or have recently taken any of the following medications:
- Aspirin or other anti-inflammatory drugs
- Anticoagulants
- Digoxin
- Methotrexate
- Cyclosporine
- Lithium
- Diuretics
- Medication for diabetes
- Medicines for blood pressure
- Rifampin or rifabutin
- Carbamazepine
- Phenytoin
- Primidone
- Phenobarbitone
- Aminoglutethimide
- Ephedrine

-Hydroxocobalamin
Rare cases of allergic reactions occurred after injection.
Local reactions by intramuscular injections
Intramuscular administration of drugs may cause changes at the site of application, which may be related to the medication used, the technique of application and/or individual patient factors. Local undesirable effects have been described at the site of application, such as pain post-injection, induration and exceptionally abscess and necrosis. If you notice redness, hardening, or pain in the area of application, immediately consult with your doctor.

How to keep DIFEN B12?
- Store between 15 and 30°C.
- Keep away from the reach of children

Presentation
Boxes with 3 and 5 ampoules.
If you apply higher doses of DIFEN B12 than those you should apply
In the event of an overdose, go to the nearest Hospital or contact the toxicological centers:
Hospital A. Posadas: (011) 4654-6648/4658-7777. Pediatric Hospital Ricardo Gutierrez: (011) 4962-6666/2247. Optionally other toxicological centers.

"This medication has been prescribed only for your current medical problem. Do not recommend to others".
"In case of any problem with the product the patient can fill in the form that is on the website of the ANMAT
http://anmat.gov.ar/farmacovigilancia/Notificar.asp or call to
ANMAT answer at 0800-333-1234 "

Technical Director: Dr. Luis M. Radici -Pharmacist.
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