ALFECTA

Instructions
on medical use of the drug

Tradename: Alfecta.
International nonproprietary name: Combination drug.
Dosage form: Solution for intramuscular administration.
Compound:
2 ml of injection solution A contain:
Dexamethasone 3.32 mg;
Phenylbutazone 375.00 mg;
Excipients:
lidocaine hydrochloride 4 mg; sodium hydroxide 49.08 mg; sodium acetic acid salicylamide 150.00 mg; water for injection 1675.92 mg.
1 ml of injection solution B contains:
Cyanocobalamin (vitamin B12) 2.5 mg;
Excipients:
lidocaine hydrochloride 2 mg; water for injection 996.5 mg.
ATX code: M01BA01.
Clinical and pharmacological group:
A combined product containing corticosteroids and NSAIDs (solution A), vitamins (solution B).
Pharmacological properties:
Pharmacodynamics:
Combined drug. It has anti-inflammatory, antipyretic, analgesic effects.
Dexamethasone is a glucocorticosteroid that has a pronounced anti-inflammatory effect.
Phenylbutazone is an NSAID that has anti-inflammatory, analgesic and antipyretic effects, and causes a uricosuric effect.
Cyanocobalamin (vitamin B12) – activates the synthesis of nucleic acids. Acetic acid Sodium salicylamide has an analgesic effect and also promotes better solubility of the drug.
Lidocaine hydrochloride - allows you to make the injection painless.
Pharmacokinetics:
After intramuscular administration, dexamethasone is rapidly absorbed into the systemic circulation. Phenylbutazone has a high degree of binding to plasma proteins, metabolic breakdown occurs slowly, providing a long half-life of 18-21 hours. Dexamethasone and phenylbutazone penetrate the placenta and are excreted in breast milk.
Cyanocobalamin: After intramuscular injection, cyanocobalamin is quantitatively and rapidly absorbed, with plasma levels reaching their peak within 1 hour. After absorption, cyanocobalamin is transported through specific cyanocobalamin -

binding proteins, transcobalamin I and II, into various tissues. The liver is the main organ for storing cyanocobalamin.
48 hours after administration of cyanocobalamin, 50 to 98% of the administered dose may appear in the urine. The main part is eliminated from the body during the first 8 hours.
Indications for use: Short-term symptomatic treatment of such acute conditions as:

- articular syndrome with rheumatoid arthritis, osteoarthritis, gout;
- neuritis, neuralgia, radiculitis (including with degenerative diseases of the spine) and others.

Contraindications:

- acute gastritis, pancreatitis, peptic ulcer of the stomach and duodenum;
- c heart failure, acute myocardial infarction;
- dysfunction of the thyroid gland, kidneys and liver;
- glaucoma;
- Sjögren's syndrome;
- lupus erythematosus;
- chronic arthritis;
- bacterial infections;
- thromboembolism;
- pregnancy and lactation;
- children under 14 years of age;
- elderly age.

Directions for use and dosage:
The drug is prescribed 1 injection per day or every other day, no more than 3 injections per week. When repeating courses of treatment, the interval between them should be at least 2 weeks. The injection is made deep intramuscularly, slowly. The patient should be in a horizontal position. First, solution A is drawn into the syringe, then solution B. The temperature of the solution should be close to body temperature.
Side effects: dizziness, headache, sleep disturbance.
Rarely - psychosis, decreased vision, hearing and appetite, abdominal pain, vomiting, diarrhea, impaired liver and kidney function, bradycardia, arterial hypotension, orthostatic collapse, leukopenia, thromboembolism, narrowing of the airways, anuria, rarely - local pain in the injection area, mycosis, fever.
Interaction with other drugs:
When using the drug Alfecta simultaneously:
- with other anti-inflammatory drugs, with drugs containing ethanol, with indirect coagulants and heparin, sulfinpyrazone, the risk of bleeding from the gastrointestinal tract increases;
- hyper- or hypoglycemia is possible with hypoglycemic agents or insulin;
- with fenithion it is possible to increase the toxicity of the latter;
- with cardiac glycosides it is possible to slow down or accelerate dedigitalization;
- with antihypertensive drugs, the effect of the latter is reduced;

diuretics, it is possible to reduce diuresis and develop hypo- or hyperkalemia;
- anabolic steroids enhance the effect of Alfect;
- Alfecta enhances the hypnotic effect of barbiturates.

Overdose:

Symptoms: nausea, vomiting, abdominal pain, gastrointestinal bleeding, dizziness, headache, arterial hypotension, liver and kidney failure, bradycardia, cerebral and pulmonary edema, leukopenia, aplastic anemia, heart failure, convulsions, coma.
Treatment: artificial ventilation and other resuscitation measures; according to indications, anticonvulsants (for example: intravenous diazepam); hemodialysis.

Pregnancy and breastfeeding:

The drug is contraindicated for use during pregnancy and breastfeeding.

Special instructions:

The drug should be prescribed with caution to patients with impaired renal function, diabetes mellitus, tuberculosis, epilepsy, mental illness, bronchial asthma, chronic bacterial infections, arterial hypertension or hypotension, thromboembolism.
Before starting a course of treatment, a thorough examination of the patient should be carried out in order to exclude peptic ulcers of the stomach and duodenum, kidney and liver diseases.
The injection must be made deeply, in different areas, under sterile conditions.
Patients receiving anticoagulants simultaneously with Alfecta should systematically analyze their blood clotting parameters, taking into account the risk of bleeding.
Phenylbutazone affects the results of thyroid function tests, so appropriate tests should be carried out no earlier than 2 weeks after stopping treatment with Alfecta.
Medicines containing cyanocobalamin (Alfecta) may distort clinical and laboratory parameters in patients with funicular myelosis and pernicious anemia.

Release form:

Ampoules No 3+3 (solution A , 2 ml in ampoules No. 3 and solution B, 1 ml in ampoules No 3) in a cardboard box.

Storage conditions:

Store in a dry place, protected from light, at a temperature not exceeding 25 °C and out of reach of children.

Best before date:

3 years. Do not use after expiration date.

Vacation conditions:

By doctor's prescription.

Made for:
MAXX PHARM LTD.
London, Great Britain