GIPOTAZON

Instructions for the medicinal product

Trade name: Gipotazon.
International nonproprietary name: Betamethasone.
Dosage form: Solution for injection.
Composition: Each ml contains:

Betamethasone Sodium Phosphate BP eq. to Betamethasone	4 mg;
Phenol BP	0.5% w/v.
(As Preservative)	
Water for Injection BP	q.s.

Pharmacotherapeutic group: Corticosteroids for systemic use. Glucocorticoids.
ATC Classification: H02AB01.
Pharmacologic property:
Pharmacodynamics:
Betamethasone is a glucocorticoid and has the general properties of corticosteroids. It acts by controlling the rate of protein-synthesis. It forms a steroid-receptor complex with receptor proteins, moving into the nucleus where it binds the chromatin and regulates transcription of certain genes. In most examples transcription is enhanced, never the less glucocorticoids also decrease transcription of certain genes i.e. pro-opiomelanocortin that encodes ACTH.
Pharmacokinetics:
Betamethasone is rapidly distributed to all body tissues and plasmaprotein binding is high. It crosses the placenta and may be excreted in small amounts in breast milk. Betamethasone is metabolised mainly in the liver but also in the kidney, and is excreted in the urine.
Indications:
For parenteral use:
- Shock (burns, traumatic, operations, toxic, cardiogenic, blood transfusion, anaphylactic);
- Allergic reactions (acute, severe), anaphylactoid reactions;
- Brain swelling (brain tumor or associated with surgery, radiation therapy, or a head injury), increased intracranial pressure;
- Bronchial asthma (severe), asthma status;
- Systemic connective tissue diseases (systemic lupus erythematosus, rheumatoid arthritis);
- Acute adrenal insufficiency, prevention of adrenal insufficiency in patients who received corticosteroids for a long time;
- Thyrotoxic crisis, acute hepatitis, hepatic coma;
- Poisoning cauterizing liquids;
- Diphtheritic croup (in combination with an appropriate antimicrobial therapy).

For intra-articular administration:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteochondritis, acute gouty arthritis;
- Diseases of the soft tissues (including bursitis, fibrositis, tendinitis, tenosynovitis, myositis).

Contra-indications:
- Hypersensitivity to any of the ingredients;
- Patients with osteoporosis; psychosis; severe psychoneuroses;
- Patients with peptic ulcer, doubtfully quiescent or active tuberculosis and in patients suffering from acute viral infections including herpes zoster or herpes simplex ulceration of the eye;
- Pregnancy and lactation;
- Patients should not be vaccinated with live vaccines while being treated with betamethasone.

Dosage and directions for use:
Intravenously, intramuscularly, intra-articularly, intralesionally or by infusion in doses equivalent to 4 mg to 20 mg betamethasone. It may also be used by local injection into soft tissue, in doses equivalent to 4 mg to 8 mg.
Dosage frequency and route of administration must be adjusted to the specific requirements of the patient, according to the disease, the severity of the condition, the response obtained and the patients tolerance to the product.
Gipotazon IV bolus or drip - slow:
Adults: 4-8 mg single dose (if necessary -20 mg), followed by a maintenance dosage 2-4 mg.
Gipotazon IM deep:
*Adults:*4-6 mg (9 mg) per day. *Children* – IM injection, *1 to 5 years* - an initial dose of 2 mg, *6-12 years* - 4 mg.
Intra-articular and periarticular (adults): large joints of 2-4 mg (9 mg), small 0.8-2 mg not more than 1 time in 3 weeks, and in the bursa of 2-3 mg; tendon sheath 0.4-1 mg; soft tissue 2-6 mg; VC intralesional 0.1 mg/cm2 (not more), not more than 2 mg per week, if necessary mixed with a local anesthetic (1% lidocaine, procaine).
Rapid intravenous injection of massive doses of corticosteroids may sometimes cause cardiovascular collapse and injections should therefore be given slowly or by infusion.
Side-effects:
Electrolyte disturbances are characterized by hypertension and oedema, because of the retention of sodium and water, and the increase in potassium, excretion may cause hypokalaemic alkalosis. Increased susceptibility to all kinds of infection; sepsis; tuberculosis; fungal infections; viral infections and delayed wound healing. Acute adrenal insufficiency may occur during prolonged therapy or on cessation and may be precipitated by stressful situations. Growth retardation in children. High doses during pregnancy may cause foetal or neonatal adrenal suppression. Reversible Cushingoid symptoms may be produced with large doses. Due to mobilisation of calcium and phosphorus, osteoporosis and spontaneous fractures, nitrogen depletion, and hyperglycaemia may occur. Other side-effects ; amenorrhoea, hyperhidrosis, skin thinning, ocular changes including development of cataract, mental and neurological disturbances, intracranial hypertension, acute pancreatitis, muscle weakness and aseptic necrosis of bone. Increased coagulability of the blood may lead to thrombo-embolic complications. Care should be taken in patients with congestive heart failure; hypertension; diabetes mellitus; epilepsy; glaucoma; infective diseases; ocular herpes simplex, chronic renal failure; uraemia and in elderly patients. Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged.
Overdose:
Symptoms: acute overdose of betamethasone does not lead to life-threatening situations. Introduction to a few days of GCS in high doses does not lead to undesirable consequences, except with very high doses, or when used in diabetes, glaucoma, worsening erosive and ulcerative lesions of the gastrointestinal tract or the simultaneous use of digitalis drugs, anticoagulants or diuretics, potassium excretory .
Treatment: In case of an acute overdose, maintain adequate fluid intake and monitor electrolytes in serum and urine, with particular attention to sodium and potassium balance. If necessary, carry out the appropriate therapy.
Drug interaction:
Simultaneous administration of barbiturates, carbamazepine, phenytoin, primidone, or rifampicin may reduce the effect of corticosteroids.
Antimuscarinic effects may be decreased in myasthenia gravis.
It interferes with assay procedures for endogenous substances.
Excessive potassium loss may be due to concurrent administration of corticosteroids with potassium-depleting diuretics e.g. furosemide.
When corticosteroids are given with non-steroidal anti-inflammatory agents, an increase incidence of gastro-intestinal bleeding and ulceration may occur.
Serum concentrations of salicylates may be decreased.
Requirements of antidiabetics and antihypertensives may be increased.
Cautions:
The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual.
Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.
Cardio-renal.
As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.
Endocrine.
Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy. Therefore, in any situation of stress occurring during that period, naturally occurring glucocorticoids, which also have salt-retaining properties, rather than betamethasone, are the appropriate choices as replacement therapy in adrenocortical deficiency states.
Gastrointestinal.
Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of a perforation.
Signs of peritoneal irritation following gastrointestinal perforation in patients receiving corticosteroids may be minimal or absent.
There is an enhanced effect of corticosteroids in patients with cirrhosis.
Appropriate examination of any joint fluid present is necessary to exclude a septic process.
A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of septic arthritis. If this complication occurs and the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted.
Injection of a steroid into an infected site is to be avoided. Local injection of a steroid into a previously injected joint is not usually recommended.
Corticosteroid injection into unstable joints is generally not recommended.
Intra-articular injection may result in damage to joint tissues.
Musculoskeletal.
Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation (ie, decreasing absorption and increasing excretion) and inhibition of osteoblast function. This, together with a decrease in the protein matrix of the bone secondary to an increase in protein catabolism, and reduced sex hormone production, may lead to inhibition of bone growth in pediatric patients and the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (ie, postmenopausal women) before initiating corticosteroid therapy.
Neuropsychiatric.
Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that they affect the ultimate outcome or natural history of the disease. The studies do show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect.
An acute myopathy has been observed with the use of high doses of corticosteroids, most often occurring in patients with disorders of neuromuscular transmission (eg, myasthenia gravis), or in patients receiving concomitant therapy with neuromuscular blocking drugs (eg, pancuronium). This acute myopathy is generalized, may involve ocular and respiratory muscles, and may result in quadriparesis. Elevation of creatinine kinase may occur. Clinical improvement or recovery after stopping corticosteroids may require weeks to years.
Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.
Ophthalmic.
Intraocular pressure may become elevated in some individuals. If steroid therapy is continued for more than 6 weeks, intraocular pressure should be monitored.
Presentation:
1 ml x 5 amps in carton box, with instruction for use.
Storage:
Keep in dry place protected from light at a temperature below 25°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Prescribed medicine.

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