Triamon

Triamcinolone Acetonide BP

Presentation

Each vial of suspension contains Triamcinolone Acetonide BP 40 mg/ml.

Description

Triamcinolone Acetonide is a synthetic glucocorticoid corticosteroid with marked anti-inflammatory action which also have salt retaining properties are used as replacement therapy in adrenocortical deficiency states. So it is primarily used for their potent anti-inflammatory effects in disorder of many organ systems.

Indication

IM: The IM administration of **Triamon** (Sterile Triamcinolone Acetonide Suspension BP) is indicated for systemic corticosteroid therapy in such conditions as allergic diseases, dermatoses, generalized rheumatoid arthritis, neurologica disorder, nervous system and hematologic disorder. Intramuscular administration is particularly valuable when oral corticosteroid therapy is not feasible.

Intra-Articular: The Intra-articular administration of **Triamon** Injection is indicated for adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in synovitis of osteoarthritis, rheumatoid arthritis, acute and subacute bursitis, acute gouty arthritis, epicondylitis, acute nonspecific tenosynovitis and post-traumatic osteoarthritis.

Dosage and Administration

Dosage

General: The initial dosage should be maintained or adjusted. The initial dose of **Triamon** Injection may vary from 2.5 to 60 mg per day depending on the specific disease entity being treated. However, acute, life-threatening situations, administration of dosages exceeding the usual doses may be justified. It should be emphasized that dosage must be individualized on the basis of the disease under treatment and the response of the patient.

Systemic: In maintenance therapy, patient-to-patient response is not uniform. Therefore, the dose must be individualized for optimal control. For *adults and children over 12 years of age,* the suggested initial dose is 60 mg, injected deeply into the gluteal muscle. Subcutaneous fat atrophy may occur if care is not taken to inject the preparation intramuscularly. Dosage is usually adjusted within the range of 40 to 80 mg, depending upon patient response and duration of relief. However, some patients may be well controlled on dosage as low as 20 mg or less. For *children (6 to 12 years),* the suggested initial dose is 40 mg, although dosage depends on the severity of symptoms than on age or weight. There is insufficient clinical experience with **Triamon** Injection to recommend its use in children under 6 years of age.

Local: For Intra-articular administration and for injection into tendon sheaths, the initial dose of **Triamon** Injection may vary from 2.5 to 5 mg for smaller joints and from 5 to 15 mg for larger joints depending on the specific disease entity being treated. For adults, doses up to 10 mg for smaller areas and up to 40 mg for larger areas have usually been sufficient to alleviate symptoms. Single injections into several joints for multiple locus involvement, up to a total of 80 mg have been given. Generally, a single local injection of Triamcinolone Acetonide is frequently sufficient, but several injections may be needed for adequate relief of symptoms. The site of the injection and the volume of the injection should be carefully considered when Triamcinolone Acetonide is administered.

Administration

It is mandatory to follow strict aseptic technique

General: Before use, the vial should be shaken to ensure a uniform suspension. Prior to withdrawal, the suspension should be checked for clumping or granular appearance.

Systemic: For systemic therapy, injection should be made deeply into the gluteal muscle to ensure IM delivery. For adults, a minimum needle length of 38 mm is recommended

Local: The usual Intra-articular technique should be followed for the treatment of joints. If an excessive amount of synovial fluid is present in the joint, some, not at all, should be aspirated to aid in the relief of pain and to prevent undue dilation of the corticosteroids.

Contraindication

Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura. **Triamon** is also contraindicated in patients with a sensitivity to any components of this product.

Adverse Reaction

Following Administration by any route - patients should be suprvised closely for the following adverse reactions which may be associated with any corticosteroid therapy:

General - anaphylactoid reactions; aggravation or masking of infections.

Cardiovascular - hypertension, syncope, congestive heart failure, arrthymias, necrotising angiitis, thromboembolism, thrombophlebitis.

Fluid and electrolyte disturbances - sodium retention, fluid retention associated with hypertension and congestive heart failure in susceptible patients, potassium loss, cardiac arrhythmias or ECG changes due to potassium deficiency, hypokalemic alkalosis and hypertension.

Musculoskeletal - muscle weakness, fatigue, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, delayed healing of fractures, aseptic necrosis of femoral and humeral heads, pathologic fractures of long bones and spontaneous fractures.

Gastrointestinal - peptic ulcer with possible subsequent perforation & haemorrhage, pancreatitis, abdominal distension and ulcerative oesophagitis.

Dermatological - impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, purpura, striae, hirsutism, acneiform eruptions, lupus erythematous-like lesions and suppressed reactions to skin tests.

Neurological - convulsions, increased intracranial pressure with papilloedema (pseudo-tumour cerebri) usually after treatment, vertigo, headache, neuritis or paresthesias, and aggravation of pre-existing psychiatric conditions, depression (sometimes severe), euphoria, mood swings, psychotic symptoms and personality changes.

Endocrine - menstrual irregularities, development of the cushingoid state, suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g. trauma, surgery, or illness); decreased carbohydrate tolerance; manifestations of latent diabetes mellitus and increased requirements for insulin or oral hypoglycaemic agents in diabetics.

Ophthalmic - posterior subcapsular cataracts, increased intraocular pressure, glaucoma and exophthalmos.

Metabolic - hyperglycemia, glycosuria and negative nitrogen balance due to protein catabolism.

Others - necrotising angiitis, thrombophlebitis, thromboembolism, aggravation or masking of infections, insomnia, syncopal episodes and anaphylactoid reactions.

Following Intramuscular Administration - Severe pain has been reported in a few cases. Sterile abscess formation, subcutaneous and cutaneous atrophy, hyperpigmentation and hypopigmentation and charcot-like arthropathy have also occurred.

Following Intra-Articular Administration - Undesirable reactions have included postinjection flare, transient pain, occasional irritation at the injection site, sterile abscess formation, hyperpigmentation and hypopigmentation, charcot-like arthropathy and occasional brief increase in joint discomfort.

Use in the elderly

The common adverse effects of systemic corticosteroids such as osteoporosis or hypertension may be associated with more serious consequences in old age. Close clinical supervision is recommended.

Use in Pregnancy & Lactation

Many corticosteroids have been shown to be teratogenic in laboratory animals at low doses. Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers, or women of child bearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and the embryo, fetus or nursing infant. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Use in children

As corticosteroids can suppress growth, the development of infants and children on prolonged corticosteroid therapy should be carefully observed. Caution should be taken in the event of exposure to chicken pox, measles or other communicable diseases. Children should not be vaccinated or immunized while on corticosteroid therapy. Corticosteroids may also affect endogenous steroid production.

Drug interaction

Corticosteroids can increase the chance of bleeding from the gut caused by Aspirin, Ibuprofen or other NSAIDs. Some medicine used to treat epilepsy, tuberculosis or breast cancer can reduce the effectiveness of Triamcinolone. It can affect the action of some medicines of diabetes, high blood pressure-to slow the heart or to thin the blood. Always consult with the doctor before taking oral contraceptives, hormone replacement therapy, growth hormone, thyroid drugs, cyclosporine, medicine for treating fungal infections or be vaccinated or to be given an anesthetic. There is no known interaction between Triamcinolone and alcohol.

Overdose

The symptoms of glucocorticoid overdose may include confusion, anxiety, depression, gastrointestinal cramping or bleeding, ecchymosis, moon face and hypertension. After long-term use, rapid withdrawal can result in acute adrenal insufficiency. In acute case, there is no specific treatment for overdose, but supportive therapy should be instituted if gastrointestinal bleeding occurs, it should be managed.

Storage Condition

Must be stored in a dark place below 30° C. It must be kept upright and must not be frozen.

Packaging

Box containing 1 x 5's vials of injectable suspension in blister strip.

Manufactured by :
GLOBE PHARMACEUTICALS LTD.
BANGLADESH.