Export Malaysia

11 cm

17 cm

KANOLONE - F

INJECTION

LF-0151

Description : KANOLONE-F is a sterile, white suspension for injection providing Triamcinolone Acetonide which is a synthetic corticosteroid with marked anti-inflammatory action.

Composition : Each mL contains :

Active Ingredient : Triamcinolone Acetonide 40 mg

Other Ingredients : Sodium CMC, Polysorbate 80, Benzyl Alcohol, Sodium Chloride, Water for Injection

Indication :

1. For Intra-articular (IA), Intrabursal (IB) administration and for injection into tendon sheaths as adjunctive therapy for short-term administration in : arthritic disorder .
2. For Intramuscular (IM) administration indicated for endocrine disorders, collagen diseases, dermatologic diseases, allergic disorders.

Pharmacodynamics :

Triamcinolone Acetonide is a synthetic glucocorticoid with marked anti-inflammatory action. It has varied metabolic effects common to cortisone-like drugs. The body's immune responses to diverse stimuli are also modified by its action.

KANOLONE-F Injection has an extended duration which may be permanent or sustained for several weeks Studies indicate that following a single intramuscular dose of 60 to 100 mg of Triamcinolone Acetonide, adrenal suppression occurs within 24 to 48 hours and then gradually returns to normal, usually in 30 to 40 days. This finding correlates closely with the extended duration of therapeutic action achieved with the drug.

Pharmacokinetics :

Corticosteroids in the circulation are extensively bound to plasma proteins, mainly to globulin and less so to albumin. The corticosteroid-binding globulin has high affinity but low binding capacity, while the albumin has low affinity but large binding capacity. Only unbound corticosteroid has pharmacological effects or is metabolized. Corticosteroids are metabolized mainly in the liver but also in the kidney, and are excreted in the urine.

Dosage and Administration :

Intramuscular administration:

For adults and children over 12 years of age, the suggested initial dose is 60 mg, injected deeply into gluteal muscle. Dosage is usually adjusted within the range of 40 to 80 mg.

For children from 6 to 12 years of age, the suggested initial dose is 40 mg, although dosage depends more on the severity of symptoms than on age or weight.

Local administration:

For intra-articular and intrabursal administration, and for injection into tendon sheaths or ganglia, dosage of this product is dependent on the severity of the symptoms and on the size of the joint or other localised area to be treated.

For adults, doses up to 10 mg for smaller areas and up to 40 mg for large areas have usually been sufficient to alleviate symptoms. Single injection into several joints for multiple locus involvement, up to a total of 80 mg has been given without undue reactions.

Shake the vial before use to ensure a uniform suspension. To be administered by a physician.

Over dosage :

Symptoms : There are two categories of toxic effects for therapeutic use of glucocorticoids: Acute adrenal insufficiency due to too rapid withdrawal of corticosteroids after long-term use resulting in fever, myalgia, arthralgia, malaise, anorexia, nausea, desquamation of skin, orthostatic hypotension, dizziness, fainting, dyspnea and hypoglycemia.

Cushingoid changes from continued use of large doses resulting in moonface, central obesity, striae, hirsutism, acne ecchymoses, hypertension. Osteoporosis, myopathy, sexual dysfunction, diabetes, hyperlipidemia, peptic ulcer increased susceptibility to infection and electrolyte and fluid imbalance. Reports of acute toxicity or death are rare.

Treatment : Recovery of normal adrenal and pituitary function may require up to 9 months.

Gradually taper the steroid under the supervision of a physician. Frequent lab tests are necessary.

Supplementation is required during periods of stress (e g. illness, surgery, injury). Eventually reduce to the lowest dose that will control the symptoms or discontinue the corticosteroid completely. For large, acute overdoses treatment includes that gastric lavage or emesis and usual supportive measures.

Drug Interaction :

Concurrent administration of barbiturates, phenylbutazone, phenytoin, or rifampicin may enhance the metabolism and reduce the effects of corticosteroids.

Response to anticoagulants may also be reduced by corticosteroids.

Potassium-depleting diuretics (e.g. thiazides, furosemide, ethacrynic acid) and other drugs that deplete potassium, such as amphotericin B, may enhance the potassium-wasting effect of glucocorticoids. Serum potassium should be closely monitored in patients receiving glucocorticoids and potassium-depleting drugs.

Interaction between glucocorticoids and anticholinesterase agents such as ambenonium neostigmine or pyridostigmine (and presumably organophosphate anticholinesterase pesticides) can produce severe weakness in patients with myasthenia gravis. If possible, anticholinesterase medication should be withdrawn at least 24 hours prior to initiation of glucocorticoid therapy.

Rarely, cortisone had been reported to increase blood coagulability and to increase anticoagulant dosage requirements in patients stabilized on oral anticoagulant therapy.

Corticosteroids may decrease glucose tolerance, produce hyperglycemia and aggravate or precipitate diabetes mellitus especially in patients predisposed to diabetes mellitus. If steroid therapy is required in patients with diabetes mellitus, changes in insulin or oral antidiabetic agent dosage or diet may be necessary.

Since glucocorticoid therapy can reactivate tuberculosis, chemoprophylaxis should be included in the regimen of patients with a history of active tuberculosis undergoing prolonged glucocorticoid therapy. In the treatment of acute or disseminated tuberculosis, glucocorticoids should only be used as part of a total antituberculosis regimen.

Seizures reportedly have occurred in adult and pediatric patients receiving high-dose corticosteroid therapy concurrently with cyclosporine.

Effects of other glucocorticoids that bind to transcortin could be similarly potentiated and dosage adjustments may be required if estrogens are added to or withdrawn from a stable dosage required.

Aspirin should be used cautiously in conjunction with glucocorticoids in patients with hypoprothrombinemia. Although concomitant therapy with salicylates and concosteroids does not appear to increase the in cadence or severity of GI ulceration, the possibility of this effect should be considered.

Serum salicylate concentrations may decrease when corticosteroids are administered concomitantly. Likewise, when corticosteroids are discontinued in patients receiving salicylates, serum salicylate concentration may increase; salicylate intoxication has been precipitated rarely.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Contraindications :

Patients with systemic fungal infections, idiopathic thrombocytopenic purpura and to patients which are sensitive to any of its ingredients. Osteoporosis, active peptic ulcer, psychosis or severe psychoneurosis systemic fungal infections. Patients should not undergo immunizations. Tuberculosis, except as adjunctive treatment with tuberculostatic drugs. Because of interference with antibody formation, systemic administration if corticosteroids is usually contraindicated in the presence of acute bacterial infections, herpes zoster, herpes simplex, ulceration of the eyes, and other viral infections. Vaccination against smallpox and other infections is also contraindicated.

Effects on ability to drive and use machine : Not relevant.

Side Effects

The following adverse reactions may be associated with corticosteroid therapy:

Allergic reactions: Anaphylaxis including death, angioedema.

Cardiovascular: Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.

Dermatologic : Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypo-pigmentation, impaired wound healing, increased sweating, lupus erythematosus-like lesions, purpura, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

Endocrine : Decreased carbohydrate and glucose tolerance, development of cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, postmenopausal vaginal hemorrhage, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients.

Fluid and Electrolyte Disturbances : Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention.

Gastrointestinal: Abdominal distention, elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.

Metabolic: Negative nitrogen balance due to protein catabolism.

Musculoskeletal : Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, post injection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.

Neurologic/ Psychiatric : Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychiatric disorders, vertigo. Arachnoiditis, meningitis, paraparesis/paraplegia, and sensory disturbances have occurred after intrathecal administration.

Spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke (including brainstem) have been reported after epidural administration of corticosteroids.

Ophthalmic: Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, rare instances of blindness associated with periocular injections.

Other: Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.

Shake well before using. For IA, IM, and IB injection and should not be administered Intravenously (IV).

Warning & Precautions

General precautions:

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.

Intra-Articular and Soft Tissue Administration

Intra-articularly injected corticosteroids may be systemically absorbed.

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 infected joint is not usually recommended.

Corticosteroid injection into unstable joints is generally not recommended.

Intra-articular injection may result in damage to joint tissues.

Warnings:

KANOLONE-F Injection is a suspension, it should not be administered intravenously.

Unless a **deep** intramuscular injection is given, local atrophy is likely to occur.

Due to the significantly higher incidence of local atrophy when the material is injected into the deltoid area, this injection site should be avoided in favor of the gluteal area.

This product contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with serious adverse events and death, particularly in paediatric patients. The "gasping syndrome" has been associated with benzyl alcohol. Although normal therapeutic doses of this product deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birth-weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity.

Use in children

Because corticosteroids can suppress growth, the development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Caution should be used in the event of exposure to chicken pox, measles or other communicable diseases. Children should not be vaccinated or immunised while on corticosteroid therapy. Corticosteroids may also affect endogenous steroid production.

Exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates, and an increased incidence of kernicterus, particularly in small preterm infants. There have been rare reports of deaths, primarily in preterm infants, associated with exposure to excessive amounts of benzyl alcohol.

Children are at specially risk from raised intracranial pressure.

Pheochromocytoma crisis, which may be fatal, has been reported after administration of systemic corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

Pregnancy and Lactation :

The use of these drugs in pregnancy or 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.

Packaging :

Vial 1 mL per box and a shrink film pack of 10 boxes.
Vial 5 mL per box and a shrink film pack of 10 boxes.

Storage :

Store below 30°C.

In-use storage :

The product should be used immediately after open. If not, use within 7 days after first puncture and store the remaining vials between 2-8°C under refrigeration or at controlled room temperature of 23-27°C.

User's Instructions :

Shake well before using. For IA , IM, and IB injection and should not be administered Intravenously (IV).

Shelf-life : 4 years

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