



For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

TRICORT 40MG/ML Injection

Triamcinolone Acetonide Injectable Suspension USP

COMPOSITION

Each ml contains:
Triamcinolone Acetonide USP 40 mg
Benzyl Alcohol NF 0.9%W/V
(As preservative)
Aqueous Base q.s.

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

Description: White, smooth, homogeneous suspension.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Triamcinolone acetonide is a synthetic glucocorticoid with marked anti-inflammatory and anti-allergic actions.

Intra-Articular Injection:

Following local injection, relief of pain and swelling and greater freedom of movement are usually obtained within a few hours.

Intramuscular Injection:

Provides an extended duration of therapeutic effect and fewer side effects of the kind associated with oral corticosteroid therapy, particularly gastro-intestinal reactions such as peptic ulceration. Studies indicate that, following a single intramuscular dose of 80 mg triamcinolone acetonide, adrenal suppression occurs within 24 - 48 hours and then gradually returns to normal, usually in approximately three weeks. This finding correlates closely with the extended duration of therapeutic action of triamcinolone acetonide.

Pharmacokinetic Properties

Triamcinolone acetonide may be absorbed into the systemic circulation from synovial spaces. However clinically significant systemic levels after intra-articular injection are unlikely to occur except perhaps following treatment of large joints with high doses. Systemic effects do not ordinarily occur with intra-articular injections when the proper techniques of administration and the recommended dosage regimens are observed.

Triamcinolone acetonide is absorbed slowly, though almost completely, following depot administration by deep intramuscular injection; biologically active levels are achieved systemically for prolonged periods (weeks to months). In common with other corticosteroids, triamcinolone is metabolised largely hepatically but also by the kidney and is excreted in urine. The main metabolism route is 6-beta-hydroxylation; no significant hydrolytic cleavage of the acetonide occurs.

In view of the hepatic metabolism and renal excretion of triamcinolone acetonide, functional impairments of the liver or kidney may affect the pharmacokinetics of the drug.

INDICATIONS

INTRAMUSCULAR

Where oral therapy is not feasible or is temporarily undesirable in the judgment of the physician, TRICORT INJECTION is indicated for intramuscular use as follows:

Endocrine disorders: Neospurative thyroiditis.

Rheumatic disorders - as adjunctive therapy for short-term administration: Post-traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; epicondylitis; acute non-specific tenosynovitis; acute gouty arthritis; psoriatic arthritis; ankylosing spondylitis; juvenile rheumatoid arthritis.

Collagen diseases - during an exacerbation or as maintenance therapy in selected cases: Systemic lupus erythematosus, acute rheumatic carditis.

Dermatologic diseases: Pemphigus; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; bullous dermatitis herpetiformis; severe seborrheic dermatitis; severe psoriasis.

Allergic states - control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: Bronchial asthma; contact dermatitis; atopic dermatitis; seasonal or perennial allergic rhinitis.

Gastrointestinal diseases: Critical phase requiring systemic therapy in ulcerative colitis, regional enteritis.

Respiratory diseases: Symptomatic sarcoidosis; berylliosis; aspiration pneumonitis.

Hematologic diseases: Acquired (autoimmune) hemolytic anemia.

Neoplastic disorders - for palliative management: Leukemias and lymphomas in adults; acute leukemia of childhood.

INTRA-ARTICULAR

TRICORT INJECTION is indicated for intra-articular or intra bursal administration, and for injections into tendon sheaths, as adjunctive therapy for short-term administration in the following conditions:

Synovitis of osteoarthritis

Rheumatoid arthritis

Acute and subacute bursitis

Epicondylitis

Acute non specific tenosynovitis

DOSAGE AND METHOD OF ADMINISTRATION

Route of administration: Injectable.

Tricort is for Intra-articular/Intramuscular injection. The safety and efficacy of administration by other routes has yet to be established. Strict aseptic precautions should be observed. Since the duration of effect is variable, subsequent doses should be given when symptoms recur and not at set intervals.

Intra-Articular Injection: For intra-articular administration or injection into tendon sheaths and bursae, the dose of Tricort Injection may vary from 5mg to 10mg (0.125-0.25ml) for smaller joints and up to 40 mg (1.0ml) for larger joints, depending on the specific disease entity being treated. Single injections into several sites for multiple joint involvements, up to a total of 80 mg, have been given without undue reactions.

It is recommended that, when injections are given into the sheaths of short tendons, Triamcinolone acetonide 10 mg/ml should be used.

Intramuscular Injection: To avoid the danger of subcutaneous fat atrophy, it is important to ensure that deep intramuscular injection is given into the gluteal site. The deltoid should not be used. Alternate sides should be used for subsequent injections.

Adults and Children over 12 Years: The suggested initial dose is 40 mg (1.0ml) injected deeply into the upper, outer quadrant of the gluteal muscle. Subsequent dosage depends on the patient's response and period of relief. Patients with hay fever or pollen asthma who do not respond to conventional therapy may obtain a remission of symptoms lasting throughout the pollen season after a single dose of 40-100 mg given when allergic symptoms appear.

Elderly: Treatment of elderly patients, particularly if long term, should be planned bearing in mind the more serious consequences of the common side effects of corticosteroids in old age, especially osteoporosis, diabetes, hypertension, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life-threatening reactions.

Children from 6-12 Years of Age: The suggested initial dose of 40 mg (1.0ml) injected deeply into the gluteal muscle should be scaled according to the severity of symptoms and the age and weight of the child. **Tricort 40** is not recommended for children under six years.

Growth and development of children on prolonged corticosteroid therapy should be carefully observed. Caution should be used in the event of exposure to chickenpox, measles or other communicable diseases.

Triamcinolone withdrawal: In patients who have received more than physiological doses of Tricort (more than one injection during a three week period), withdrawal should not be abrupt. The dose should be reduced and the dosage interval increased until a dose of not more than 40 mg and a dosage interval of at least three weeks have been achieved as the dose of systemic corticosteroid is reduced. Clinical assessment of disease activity may be needed.

Abrupt withdrawal of short-term systemic corticosteroid treatment is appropriate if it is considered that the disease is unlikely to relapse. A single dose, which is not repeated within a three-week period, is unlikely to lead to clinically relevant hpa-axis suppression in the majority of patients. However, in the following patient groups, gradual withdrawal of systemic corticosteroid therapy should always be considered.

- Patients who have had repeated courses of systemic corticosteroids.
- When a course of Tricort has been prescribed within one year of cessation of long-term therapy (months or years).
- Patients who may have reasons for adrenocortical insufficiency other than exogenous corticosteroid therapy.

CONTRAINDICATIONS

- Hypersensitivity to any of the ingredients.
- Systemic infections unless specific anti-infective therapy is employed.
- Administration by intravenous, intrathecal or intraocular injection.

PREGNANCY & LACTATION

Pregnancy

The ability of corticosteroids to cross the placenta varies between individual drugs, however triamcinolone does cross the placenta.

Administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development. There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate / lip in man. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. Hypoadrenalism may, in theory, occur in the neonate following prenatal exposure to corticosteroids but usually resolves spontaneously following birth and is rarely clinically important.

As with all drugs, corticosteroids should only be prescribed when the benefits to the mother and child outweigh the risks. When corticosteroids are essential, however, patients with normal pregnancies may be treated as though they were in the non-gravid state.

Lactation

Corticosteroids may pass into breast milk, although no data are available for triamcinolone. Infants of mothers taking high doses of systemic corticosteroids for prolonged periods may have a degree of adrenal suppression.

WARNINGS AND SPECIAL INSTRUCTIONS

Warnings

Adequate studies to demonstrate the safety of Triamcinolone acetonide use by intra-turbinal, subconjunctival, sub-tenons, retrobulbar and intraocular (intravitreal) injections have not been performed. Endophthalmitis, eye inflammation, increased intraocular pressure and visual disturbances including vision loss have been reported by intravitreal administration. Several instances of blindness have been reported following injection of corticosteroid suspensions into the nasal turbinates and intranasal injection about the head.

(Intra-Articular Injection):

Corticosteroids should not be injected into unstable joints.

Patients should be specifically warned to avoid over-use of joints in which symptomatic benefit has been obtained. Severe joint destruction with necrosis of bone may occur if repeated intra-articular injections are given over a long period of time. Care should be taken if injections are given into tendon sheaths to avoid injection into the tendon itself. Repeated injection into inflamed tendons should be avoided as it has been shown to cause tendon rupture.

Due to the absence of a true tendon sheath, the Achilles tendon should not be injected with depot corticosteroids.

(Intramuscular Injection):

During prolonged therapy a liberal protein intake is essential to counteract the tendency to gradual weight loss sometimes associated with negative nitrogen balance and wasting of skeletal muscle.

Precautions:

Intra-articular injection should not be carried out in the presence of active infection in or near joints. The preparations should not be used to alleviate joint pain arising from infectious states such as gonococcal or tubercular arthritis.

Undesirable effects may be minimised using the lowest effective dose for minimum period, and by administering the daily requirement, whenever possible, as a single morning dose on alternate days. Frequent patient review is required to titrate the dose appropriately against disease activity.

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Size : 120 x 400 mm
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Adrenal cortical atrophy develops during prolonged therapy and may persist for years after stopping treatment. Withdrawal of corticosteroids after prolonged therapy must, therefore, always be gradual to avoid acute adrenal insufficiency and should be tapered off over weeks or months according to the dose and duration of treatment. During prolonged therapy any intercurrent illness, trauma or surgical procedure will require a temporary increase in dosage. If corticosteroids have been stopped following prolonged therapy they may need to be introduced temporarily.

Patients should carry steroid treatment card, which give clear guidance on the precaution to be taken to minimise risk and which provide details of prescriber, drug, dosage and the duration of treatment.

Suppression of the inflammatory response and immune function increases the susceptibility to infections and their severity. The clinical presentation may be often be atypical and serious infections such as septicaemia and tuberculosis may be masked and may reach an advanced stage before being recognised.

Chickenpox and measles are of particular concern since these normally minor illnesses may be fatal in immunosuppressed patients.

Unless they have had chickenpox, patients receiving parenteral corticosteroids for purposes other than replacement should be regarded as being at risk of severe chickenpox. Manifestations of fulminant illness include pneumonia, hepatitis and disseminated intravascular coagulation; rash is not necessarily a prominent feature. Passive immunisation with varicella zoster immunoglobulin (VZIG) is needed by exposed non-immune patients who are receiving systemic corticosteroids or who have been within the previous 3 months; varicella zoster immunoglobulin should preferably be given within 3 days of exposure and not later than 10 days. Confirmed chickenpox warrants specialist care and urgent treatment. Corticosteroids should not be stopped and the dose may need to be increased.

Patients should be advised to avoid exposure to measles and to seek medical advice without delay if exposure occurs. Prophylaxis with normal immunoglobulin may be needed.

During corticosteroid therapy antibody response will be reduced and therefore affect the patient's response to vaccines. Live vaccines should not be administered.

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

Special Precautions:

Particular care is required when considering use of systemic corticosteroids in patients with the following conditions and frequent patient monitoring is necessary.

Recent intestinal anastomoses, diverticulitis, thrombophlebitis, existing or previous history of severe affective disorders (especially previous steroid psychosis), exanthematous disease, chronic nephritis, or renal insufficiency, metastatic carcinoma, osteoporosis (postmenopausal females are particularly at risk); in patients with an active peptic ulcer (or a history of peptic ulcer), Myasthenia gravis, Latent or healed tuberculosis; in the presence of local or systemic viral infection, systemic fungal infections or in active infections not controlled by antibiotics. In acute psychoses; in acute glomerulonephritis. Hypertension; congestive heart failure; glaucoma (or a family history of glaucoma), previous steroid myopathy or epilepsy.

Liver failure.

Corticosteroid effects may be enhanced in patients with hypothyroidism or cirrhosis and decreased in hyperthyroid patients. Diabetes may be aggravated, necessitating a higher insulin dosage. Latent diabetes mellitus may be precipitated.

Menstrual irregularities may occur, and this possibility should be mentioned to female patients. Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroids, especially when a patient has a history of drug allergies.

All corticosteroids increase calcium excretion. Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinaemia.

Use in children:

Tricort is not recommended for children under six years. Corticosteroids cause dose-related growth retardation in infancy, childhood and adolescence which may be irreversible, therefore growth and development of children on prolonged corticosteroid therapy should be carefully observed.

Use in Elderly:

The common adverse effects of systemic corticosteroids may be associated with more serious consequences in old age, especially osteoporosis, hypertension, hypokalaemia, diabetes, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life-threatening reactions.

ADVERSE REACTIONS

Where adverse reactions occur they are usually reversible on cessation of therapy. The incidence of predictable side-effects, including hypothalamic-pituitary-adrenal suppression correlate with the relative potency of the drug, dosage, timing of administration and duration of treatment.

Absorption of triamcinolone following injection by the intra-articular route is rare. However, patients should be watched closely for the following adverse reactions which may be associated with any corticosteroid therapy:

Anti-inflammatory and immunosuppressive effects; increased susceptibility and severity of infections with suppression of clinical symptoms and signs, opportunistic infections, recurrence of dormant tuberculosis.

Fluid and electrolyte disturbances: sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, cardiac arrhythmias or ECG changes due to potassium deficiency, hypokalaemic alkalosis, increased calcium excretion and hypertension.

Musculoskeletal: muscle weakness, fatigue, steroid myopathy, loss of muscle mass, osteoporosis, avascular osteonecrosis, vertebral compression fractures, delay healing of fractures, aseptic necrosis of femoral and humeral heads, pathological fractures of long bones and spontaneous fractures, tendon rupture.

Hypersensitivity: Anaphylactic reactions, angiodema, rash, pruritus and urticaria, particularly where there is a history of drug allergies.

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

Gastrointestinal: dyspepsia, peptic ulcer with possible subsequent perforation and haemorrhage, pancreatitis, abdominal distension and ulcerative oesophagitis, candidiasis.

Neurological: euphoria, psychological dependence, depression, insomnia convulsions, increased intracranial pressure with papilloedema (pseudo-tumour cerebri) usually after treatment, vertigo, headache, neuritis or paraesthesia and aggravation of pre-existing psychiatric conditions and epilepsy.

Endocrine: menstrual irregularities and amenorrhoea; development of the Cushingoid state; suppression of growth in childhood and adolescence; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g. trauma, surgery or illness); decreased carbohydrate tolerance; manifestation of latent diabetes mellitus and increased requirements for insulin or oral hypoglycaemic agents in diabetes, weight gain. Negative protein and calcium balance. Increased appetite.

Ophthalmic: posterior subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmos, papilloedema, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal diseases.

Other: necrotising angitis, thrombophlebitis, thromboembolism, leucocytosis, insomnia and syncopal episodes.

Withdrawal Symptoms and Signs:

On withdrawal, fever, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules and weight loss may occur. Too rapid a reduction in dose following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death.

Intra-Articular Injection

Reactions following intra-articular administration have been rare. In a few instances, transient flushing and dizziness have occurred. Local symptoms such as post-injection flare, transient pain, irritation, sterile abscesses, hyper- or hypo-pigmentation, Charcot-like arthropathy and occasional increase in joint discomfort may occur. Local fat atrophy may occur if the injection is not given into the joint space, but is temporary and disappears within a few weeks to months.

Intramuscular Injection:

Severe pain has been reported following intramuscular administration. Sterile abscesses, cutaneous and subcutaneous atrophy, hyperpigmentation, hypopigmentation and Charcot-like arthropathy have also occurred.

DRUG INTERACTIONS

Amphotericin B Injection and potassium-depleting agents: Patients should be observed for hypokalaemia.

Anticholinesterases: Effects of anticholinesterase agent may be antagonized.

Anticoagulants, oral: Corticosteroids may potentiate or decrease anticoagulant action. Patients receiving oral anticoagulants and corticosteroids should therefore be closely monitored.

Antidiabetics: Corticosteroids may increase blood glucose; diabetic control should be monitored, especially when corticosteroids are initiated, discontinued, or changed in dosage. Antihypertensives, including diuretics: Corticosteroids antagonise the effects of antihypertensive and diuretics. The hypokalaemic effect of diuretics, including acetazolamide, is enhanced.

Anti-tubercular drugs: Isoniazid serum concentrations may be decreased.

Cyclosporin: Monitor for evidence of increased toxicity of cyclosporine when the two are used concurrently.

Digitalis glycosides: Co-administration may enhance the possibility of digitalis toxicity. Oestrogens, including oral contraceptives: Corticosteroids half-life and concentration may be increased and clearance decreased.

Hepatic Enzyme Inducers (e.g. barbiturates phenytoin, carbamazepine, rifampicin, primidone, aminoglutethimide): There may be increased metabolic clearance of Tricort. Patients should be carefully observed for possible diminished effect of steroid, and the dosage should be adjusted accordingly.

Human growth hormone: The growth-promoting effect may be inhibited.

Ketconazole: Corticosteroid clearance may be decreased, resulting in increased effects.

Nondepolarising muscle relaxants:

Corticosteroids may decrease or enhance the neuromuscular blocking action.

Nonsteroidal anti-inflammatory agents (NSAIDs): Corticosteroids may increase the incidence and/or severity of GI bleeding and ulceration associated with NSAIDs. Also, corticosteroids can reduce serum salicylate levels and therefore decrease their effectiveness. Conversely, discontinuing corticosteroids during high-dose salicylate therapy may result in salicylate toxicity. Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinaemia.

Thyroid drugs: Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients.

Changes in thyroid status of the patient may necessitate adjustment in adrenocorticoid dosage.

Vaccines: Neurological complications and lack of antibody response may occur when patients taking corticosteroids are vaccinated.

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.

OVERDOSE

Chronic:

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 (which also may occur in times of stress); Cushingoid changes can result from continued use of large doses.

Acute:

There is no specific treatment for acute overdose, but supportive therapy should be instituted and, if gastrointestinal bleeding occurs, it should be managed.

INCOMPATIBILITIES:

The injection should not be physically mixed with other medicinal products.

PRESENTATION

Single unit 1ml USP type 1 flint tubular glass vial box.

STORAGE

Store below 30°C, protect from light. For single use only. Discard any remaining solution.

DATE OF REVISION: 15th March 2023

Reference:

1. UK summary of product characteristics **Kenalog** Intra-articular/ Intramuscular Injection.

E.R Squibb & Sons Ltd April 07. Information Complied on July 07

Manufactured by:

 **CADILA**
PHARMACEUTICALS
LIMITED

1389, Trasad Road, Dholka-382725,
Dist: Ahmedabad, Gujarat State, India.

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