after a single 40-100-mg dose.
Intra-articular or intra-synovial or intradermal injection: large joints: up to 40 mg; small joints: 2.5-10 mg; multiple joint involvement: up to a total of 80 mg; intradermal: 2-3mg depending on the size of the lesion and using the 10 mg/mL strength. No more than 5mg should be injected at any one site. If several sites are injected the total dose should not exceed 30mg and multiple sites should be 1 cm or more apart. The injection may be repeated at 1- to 2-week intervals.

PREPARATION AND ADMINISTRATION

1. Shake vial well before withdrawing medication. If clumping occurs, do not use.
2. Withdraw the required dose.
3. Give by IM injection deep into the upper outer quadrant of the gluteal muscle (avoid the deltoid). Use alternate sides for subsequent injections.

Common and serious undesirable effects

Injection-related:

•IM and intradermal: Severe local pain, sterile abscess, cutaneous and subcutaneous atrophy, hyper/hypopigmentation.

• Intra-articular: Transient pain, sterile abscess, hyper/hypopigmentation,Charcot-like arthropathy and occasional increase in joint discomfort.

Short-term use: Undesirable effects which may result from short-term use(minimise by using the lowest effective dose for the shortest time): ↑BP, Na and water retention, ↓K, High↓Ca, ↑blood glucose, peptic ulceration and perforation,psychiatric reactions, ↑susceptibility to infection, muscle weakness, tendonrupture, insomnia, ↑intracranial pressure, ↑seizure threshold, impaired healing.

SIGNIFICANT INTERACTIONS

• The following may ↑corticosteroid levels or effect:barbiturates, carbamazepine, phenytoin, primidone, rifabutin, rifampicin.

• Corticosteroids may ↑levels or effect of the following drugs (or ↑side-effects):anticoagulants (monitor INR), methotrexate (↑risk of blood dyscrasias). If using amphotericin IV monitor fluid balance and K level closely.

• Corticosteroids may ↓levels or effect of vaccines (↓immunological response, ↑risk of infection with live vaccines).

ADVERSE EFFECTS:

High doses of triamcinolonemay have a greater tendency to produce proximalmyopathy. Its effects on sodium and water retention are less than those of pre dnisolone.When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, or when given in tranasally, corticosteroids may be absorbed in sufficient amounts to cause systemic effects.

Effects on the eye. For complications and precautionsassociated with intravitreal use of triamcinolone see under Eye Disorders, Hypersensitivity. Local reactions to topical triamcinolone preparations have been attributed to the content of ethylenediamine.

However, there have also been reports ofanaphylactic shock after intra-articular or intramuscular injection of triamcinolone acetonide.

DRUG INTERACTIONS

Amphotericin B injection and potassium-depleting agents: Patients should be observed for hypokalemia.

NURSING MOTHERS

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

OVER DOSAGE:

Give supportive therapy as appropriate. Following chronic overdose, the possibility of adrenal suppression should be considered.

Storage: -Store in a cool and dry place below 25° C, Protected from Light.

Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Abbreviation : ↑ Arrow indicate the increasing sign and ↓ Arrow indicates decreasing sign.

Presentation:-

Triamcinolone Acetonide Injection IP sterile, aqueous suspension40mg /ml in a vial.

Manufactured by:

AMERICAN REMEDIES © Care & Cure with Research

American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA

Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A,
Harihar Complex, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib,
Distt. Sirmour, Himachal Pradesh-173025
E-mail: info@americanremedies.in

For the use only of a Registered Medical Practitioner or a hospital or a laboratory

℞

Triamcinolone Acetonide Injection IP

AMERICAN

TRICANORT 40 Injection

Sterile Aqueous Suspension for Intramuscular, Intra-Articular or Intradermal Injection

Composition:-

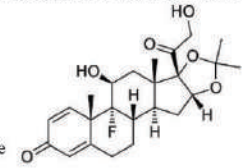
Each ml Contains:-

Triamcinolone Acetonide	IP	40 mg
Benzyl Alcohol (As Preservative)	IP	1 % v/v
Sterile aqueous base		q.s

DESCRIPTION:-

Triamcinolone acetonide Injection IP, is a synthetic glucocorticoid corticosteroid with marked anti-inflammatory action, in a sterile aqueous suspension suitable for intramuscular, intra-articular, and intra-bursal injection. This formulation is not suitable for intravenous, intradermal, intraocular, epidural or intrathecal injection.

The chemical name for triamcinolone acetonide is 9-Fluoro-11β,16α,17,21-tetrahydroxypregna1,4-diene-3,20-dione cyclic 16,17-acetal with acetone. Its structural formula is:



Triamcinolone acetonide

CLINICAL PHARMACOLOGY

Glucocorticoids, naturally occurring and synthetic, are adrenocortical steroids that are readily absorbed from the gastrointestinal tract. Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Synthetic analogs such as triamcinolone are primarily used for their anti-inflammatory effects in disorders of many organ systems.

PHARMACOLOGY

Triamcinolone is reported to have a half-life in plasma of about 2 to over 5 hours. It is bound to plasma albumin to a much smaller extent than hydrocortisone.The acetonide, diacetate, and hexacetonide esters of triamcinolone are only very slowly absorbed from injection sites.

Triamcinolone crosses the placenta.

DOSAGE AND ADMINISTRATION

Triamcinolone is a corticosteroid with mainly glucocorticoid activity; 4 mg of triamcinolone is equivalent inanti-inflammatory activity to about 5 mg of prednisolone. It is used, either in the form of the free alcohol or in one of theesterified forms, in the treatment of conditions for which corticosteroid therapy is indicated, except adrenocortical insufficiency for which hydrocortisone with supplementary fludrocortisone is preferred.

For parenteral use the acetonide ester is given in doses ofabout 40 to 80 mg by intramuscular injection. It is usually given as a suspension to provide a prolongedsystemic effect. A single dose of 40 to 100 mg of the acetonide may provide symptomatic control throughout the pollen season for hay fever sufferers. The diacetate ester has also been give nintramuscularly.

For intra-articular injection triamcinolone acetonide,diacetate, and hexacetonide have all been used. Doses for these esters have typically been in the range of 2.5 to 40 mg,depending upon the size of the joint injected.

For topical application in the treatment of various skin disorders triamcinolone acetonide is used, usually in creams, lotions, or ointments containing 0.1 % although concentrations ranging from 0.025 to 0.5 % have been employed. Several topical preparations also contain anantimicrobial drug.

For recommendations concerning the correct use of corticosteroids on the skin, and a rough guide to the clinical potencies of topical corticosteroids,

Triamcinolone esters are also commonly used by intralesional or intradermal injection in the treatment of some inflammatory skin disorders such as keloids.

Suggested doses for the various esters have been:

acetonide: 1 to 3 mg per site with no more than 5 mg injected into any one site or not more than 30 mg in total if several sites of injection are used.

Further doses may be given as needed during the course of treatment. A dose of 1 to 4 mg may be used for visualisation during vitrectomy.

For doses used in children.

DOSE

Intramuscular: initially 40mg repeated at intervals according to patient response, maximum single dose 100 mg. Patients with hay fever may gain remission of symptoms lasting throughout the season