

pharmaniaga®
TRINCORT TABLET 4MG

PRODUCT DESCRIPTION

Clean, dry, round, uniform, flat, bevel edged tablets and scored on one side.
Colour: White to off white.

Each tablet contains Triamcinolone 4mg.

Source of Lactose: Bovine

ROUTE OF ADMINISTRATION

Oral

PHARMACODYNAMICS

Pharmacotherapeutic group: ATC code: H02AB08.

Intermediate-acting corticosteroid with a potent glucocorticoid activity (anti-inflammatory, immunosuppressant and metabolic effects) and almost no mineralocorticoid activity.

Mechanism of action

Triamcinolone like other adrenocorticoids diffuses across cell membrane nucleus, binds to DNA chromatin and stimulates transcription of mRNA and subsequently the protein synthesis of various enzymes, which are considered to be responsible for the two categories effects of triamcinolone. (Glucocorticoid and mineralocorticoid).

PHARMACOKINETICS

Absorption

Triamcinolone tablet is readily and almost completely absorbed in GIT.

Distribution

Triamcinolone is extensively bound to plasma protein mainly to globulin and less so to albumin. The peak effect occurs after 1-2 hours of oral administration and may last for 2 days. The plasma half-life is about 2-5 hours and the biological tissue half-life is between 18-36 hours.

Metabolism

Triamcinolone is metabolised mainly in liver but also in the kidney.

Excretion

Triamcinolone is excreted through the urine.

INDICATIONS

Bronchial asthma, other allergic disorders, dermatoses, psoriasis (except mild, uncomplicated), nephrotic syndrome, pulmonary emphysema, pulmonary fibrosis, acute rheumatic fever, vasomotor rhinitis, urticaria, angioneurotic oedema, rheumatoid arthritis, the lymphatic leukaemias lymphosarcoma, Hodgkin's disease, disseminated lupus erythematosus. In other forms of leukaemia where for example, haemolytic anaemia or thrombocytopenia occur. Triamcinolone may be helpful. It has been used successfully in acute bursitis, sprue, uveitis and such blood dyscrasias as chronic eosinophilia, thrombocytopenic purpura and auto-immune haemolytic anaemias. The drug may also be of value when other corticosteroids have failed or have reached a limit of usefulness in steroid-responsive conditions.

RECOMMENDED DOSE

Individual requirement and the disease under treatment determine Triamcinolone dosage. A single daily dose of 4mg, given either in the morning or at bedtime depending on the clinical situation, may be satisfactory for initial or maintenance therapy in many patients; others will require a divided daily dosage regimen such as b.i.d. to q.i.d. administration. Initial daily dosage generally ranges from 8 to 32mg for adults and from 4 to 12mg for children under 25kg. Children over 25kg may be given adult dosage. It may be necessary to administer initial adult dosage in children under 25kg. After a satisfactory response, the adult dosage is reduced gradually by 2mg, every two or three days, to the optimal maintenance level. Maintenance dosage in children is regulated in terms of clinical response. Intermittent Trincort therapy employing other dosage intervals has been successful in the nephrotic syndrome and this use has also been reported in the management of juvenile rheumatoid arthritis and in certain chronic dermatoses. In addition to patient convenience, it has been suggested that once daily administration of corticosteroid is less likely to interfere with diurnal rhythm of the spontaneously secreting adrenal gland; if this is the reason for single daily dose therapy, the dose should be given in the morning. In other patients, i.e., the arthritic who complains of morning stiffness, or the asthmatic who needs protection during the night, a nocturnal dose would be desirable.

Patient transfer from other corticosteroids. Initially, substitute 4mg Trincort for each of the following:

25mg cortisone	4mg methylprednisolone
20mg hydrocortisone	0.75mg dexamethasone
5mg prednisolone	2mg paramethasone

Thereafter, dosage should be adjusted according to individual response.

TRIAMCINOLONE THERAPY GUIDE

Condition	Initial Daily	Maintenance
Bronchial Asthma	Adults: ¹ 8-16mg Children: 8-12mg	Adults: 2-8mg Children: 1-4mg
Allergic Disorders	Adults: ¹ 8-16mg Children: 4-8mg	Adults: 4-16mg Children: 2mg or less
Dermatoses ²	Adults: ¹ 8-20mg Children: 4-12mg	Adults & Children: 2mg or less
Psoriasis, ² acute exacerbations	Adults: 4-32mg (advocated for short-term control)	Adults: 1-16mg
Nephrotic Syndrome	Adults & Children: 20-48mg to diuresis (usually within 7-10 days)	Adults & Children: intermittent 8-16mg for 3 consecutive days per week
Pulmonary Emphysema pulmonary fibrosis ⁴	Adults: 8- 32mg	Adults: 1-4mg
Rheumatic fever (acute)	In divided doses Adults: 16 20mg Children: 8-10mg	Adults & Children: Gradually reduce, discontinue
Vasomotor Rhinitis	Adults: 8-16mg Children: 4-8mg	Adults: 1-4mg Children: reduce, discontinue
Urticaria	Adult ¹ & Children: 12-20mg for 5 days	Adults: Gradually reduce
Rheumatoid Arthritis	Adult ^{1a} & Children: 4-12mg	Adults: Lowest adequate dose Children: individualized
Lymphomatous disease: chronic lymphatic leukaemia	Adults & Children: 32-60mg	Adults & Children: 2-24mg
Acute lymphatic leukaemia	Children: 1mg/kg body weight	Same as initial initial dosage
Lupus erythematosus disseminated; other collagen diseases	Adults & Children: 20-32mg	Adults & Children: 4-20mg
Acute connective tissue disease (acute bursitis, myositis, fibrositis etc.)	Adults: ¹ 8-16mg	Adults: 1-8mg
Uveitis	Adults: 24-32mg	Adults: Gradually reduce
Sprue	Adults: 12-24mg Children: 3mg or more	Adults & Children: Gradually reduce

1: Single daily doses have been effectively employed

1a: A single daily dosage regimen may be tried. If response is not satisfactory, daily dosage should be given in divided amounts. If no response is observed within 7 days, consideration should be given to the possibility of an erroneous diagnosis.

2: For some chronic dermatoses, an alternate day dosage regimen, using doses equivalent to daily dosage, may be effective. Severe pemphigus requires high initial doses, even up to 100mg daily in divided doses.

3: Potent systemic steroids are not recommended for mild, uncomplicated psoriasis. Psoriasis recurs when medication is discontinued and may be more severe due to rebound phenomenon.

4: Appropriate antibiotic therapy must be given simultaneously.

CONTRAINDICATIONS

Contraindicated in patients hypersensitive to components of the formulations, in patients with systemic fungal infections or injected with live virus vaccination, active, latent or healed tuberculosis and acute psychosis.

WARNINGS & PRECAUTIONS

Use cautiously in patients with diabetes mellitus, infectious diseases, chronic renal failure, uraemia and in elderly peoples. Concurrent administration of barbiturates, phenytoin, or rifampicin may enhance the metabolism and reduce the effect of triamcinolone. Concurrent administration of potassium depleting diuretics such as thiazide or

frusemide may cause excessive potassium loss. Therapy with triamcinolone must not be withdrawn abruptly as acute adrenal insufficiency will occur.

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.

INTERACTION WITH OTHER MEDICAMENTS

The following incompatibilities / drug interactions have been selected on the basis of their potential clinical significance.

- 1) Acetaminophen (Paracetamol): Induction of hepatic enzymes by adrenocorticoids may increase the formation of a hepatotoxic acetaminophen metabolite, thereby increasing the risk of hepatotoxicity, when they are used concurrently with chronic or high-dose acetaminophen therapy.
- 2) Alcohol or anti-inflammatory analgesics, nonsteroidal (NSAIDs) risk of gastrointestinal ulceration or hemorrhage may be increased when these substances are used concurrently; however, concurrent use of NSAIDs in the treatment of arthritis may provide additive therapeutic benefit and permit glucocorticoid dosage reduction.
- 3) Amphotericin B, parenteral or carbonic anhydrase inhibitors: concurrent use may result in severe hypokalemia and should be undertaken with caution; serum potassium concentrations and cardiac function should be monitored during concurrent use.
- 4) Anticoagulants, coumarin or indandione derivative.
- 5) Heparin or Streptokinase or Urokinase.
- 6) Antidiabetic agents, oral or insulin: glucocorticoids may increase blood glucose concentration because of their intrinsic hyperglycemic activity; dosage adjustment of one or both agents may be necessary during concurrent use; dosage readjustment of the hypoglycemic agent may also be required when glucocorticoid therapy is discontinued.
- 7) Contraceptive, oral, estrogen-containing or estrogens: Estrogens may alter the metabolism and protein binding of glucocorticoids leading to decreased clearance, increased elimination half-life, and increased therapeutic & toxic effects of the glucocorticoid; glucocorticoid dosage adjustment may be required during and following concurrent use.
- 8) Digitalis glycosides: concurrent use with glucocorticoids may increase the possibility of arrhythmias or digitalis toxicity associated with hypokalemia.
- 9) Isoniazid: dosage adjustment may be required.
- 10) Diuretics
- 11) Potassium supplements: effects of these medications and/or adrenocorticoids on serum potassium concentration may be decreased when these medications are used concurrently; monitoring of serum potassium concentration is recommended.
- 12) Sodium containing medications or foods: concurrent use with pharmacologic doses of glucocorticoids may result in edema and increased blood pressure possibly to hypertensive levels; although patients receiving replacement doses of glucocorticoids may require sodium supplementation (usually as increased table salt intake), adjustment of dietary sodium intake may be required when a medication having a high sodium content is also administered concurrently.
- 13) Somatropin: inhibition of the growth response to somatrem or somatropin may occur with chronic therapeutic use of corticotropin or with daily doses (per square meter of body surface) in excess of Triamcinolone 2-3 mg. It is recommended that this dose not be exceeded during somatrem or somatropin therapy; if larger doses are required, administration of somatrem or somatropin should be postponed, also concurrent use with corticotropin is not recommended.
- 14) 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.

PREGNANCY & LACTATION

Pregnancy:

There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate/lip. 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. This medicine should be used during pregnancy only if the benefit to the mother is clearly greater than the risk to the fetus.

Lactation:

Triamcinolone has been detected in human breast milk. Because of the possibility for adverse reactions in nursing infants from triamcinolone, a choice should be made whether to stop nursing or to stop use of this medication. The importance of the drug to the mother should be considered. Use drug cautiously in breast-feeding women.

SIDE EFFECTS

Triamcinolone, like all potent steroids, should be used under close clinical supervision. Weight gain, oedema and hypertension, the usual unwanted steroid effects, usually do not occur, patients must be observed for the less obvious undesirable effects. All corticosteroids may mask symptoms of infection and permit spread of an invading organism. If questionable findings are encountered it may be advisable to interrupt triamcinolone therapy until an accurate diagnosis is made.

In acute and chronic bacterial infections, triamcinolone should only be used in conjunction with suitable antibiotic or chemotherapeutic agents. The drug should be withheld during acute viral infections, such as ocular herpes simplex and varicella. Steroid patients must be watched carefully for the development of osteoporosis and spontaneous fracture, peptic ulcer or epigastric distress. Cushingoid changes such as facial rounding, buffalo hump and other signs of fat deposition may be seen in some cases. Purpura, flushing of the face, sweating, acne, striae, hirsutism, vertigo and headache may be encountered. The growth-suppressing effects of corticosteroids in children should be considered when triamcinolone is administered to the pediatric age group.

Thromboembolism, aseptic necrosis of the hip, necrotizing angitis, acute pancreatitis and ulcerative oesophagitis are other possible side effects of steroid therapy. A liberal protein intake is essential for patients receiving triamcinolone, since it does not stimulate appetite. On prolonged therapy, most patients have a tendency to gradual weight loss, sometimes associated with negative nitrogen balance. As with all corticoids, wasting and weakness of skeletal muscle may occur in some patients. Anabolic steroids appear to be useful in maintaining nitrogen equilibrium. Diabetic patients frequently require an increase in insulin dosage; latent diabetes mellitus may become manifest during steroid therapy.

While in rare instances intracranial pressure and papilloedema have been reported to occur after administration of corticosteroids, including triamcinolone, the mechanism of action has not been elucidated. The possible association of posterior subcapsular cataracts with the administration of high dosage, long-term systemic corticosteroid therapy has been presented in the literature. For this and other reasons, long-term administration of corticoids should be kept at minimum dosage levels. In therapeutic doses, glucocorticoids depress the function of the adrenal cortex. To avoid adrenal insufficiency, therapy should be withdrawn gradually (2mg every two to three days), particularly when patients are receiving large doses or prolonged treatment. Undue stress, i.e. surgery, trauma, severe illness, during or within a year after triamcinolone treatment has been terminated calls for prompt institutions of adequate supportive measures for the duration of the stress. During treatment Triamcinolone dosage should be increased temporarily; supportive measures in the year after treatment should include ACTH and in some situations of severe stress, hydrocortisone or cortisone.

SYMPTOMS & TREATMENT OF OVERDOSAGE

Symptoms of Overdosage: CNS depression leading to coma.

Treatment for Overdosages: They should be treated symptomatically, where possible the dosage being reduced or the drug slowly withdrawn.

EFFECTS ON ABILITY TO DRIVE & USE MACHINE

Not applicable.

INSTRUCTIONS FOR USE

Should be taken with food.

PACK SIZE

Blister Pack of 10's: 50 strips of 10's

STORAGE CONDITIONS

Keep in a dry place, below 30°C; Protect from light and moisture.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

REGISTRATION NUMBER

MAL19860169AZ

CONTROLLED MEDICINE UBAT TERKAWAL

KEEP MEDICINES OUT OF REACH OF CHILDREN JAUHI UBAT-UBATAN DARI KANAK-KANAK

For further information, please consult your doctor or your pharmacist.

Revision No : 05

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Lt-072.06 Product Registration Holder and Manufacturer

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