SHI10, SHI40 MYS-005
R.O.C. Reg. No.:11476
R.O.C. Reg. No.:11475

Glucocorticoid Preparation

Shincort Injection 10mg
Shincort Injection 40mg/mL (1mL Amp)
Shincort Injection 40mg/mL (5mL Vial)

Ingredients:

SHINCORT INJECTION 10MG
Each mL contains:
Triamcinolone Acetonide 10mg
Benzyl Alcohol (as preservative) 0.02mL
Propylene Glycol (as preservative) 0.2mL

SHINCORT INJECTION 40MG/ML (1ML AMP) SHINCORT INJECTION 40MG/ML (5ML VIAL)
Each mL contains:
Triamcinolone Acetonide 40mg
Benzyl Alcohol (as preservative) 0.02mL
Propylene Glycol (as preservative) 0.3mL

Pharmacodynamic:

1. Anti-inflammatory: Inhibition of phagocytosis, leucocyte migration, and capillary dilatation occur; lysosomal membrane stabilization, decreased prostaglandin / thromboxane synthesis may possibly be mediated through the altered activity of enzymes which regulated the phospholipid content of cell membranes.
2. Immuno suppressant: Prevention or suppression of cell-mediated immune reactions may be related to the anti-inflammatory actions of Triamcinolone.
3. Metabolic: Protein catabolism provides amino acids for gluconeogenesis which, along with decreased peripheral utilization of glucose, leads to increased glycogen storage in the liver, increased blood glucose levels, and insulin resistance. Lipolysis occurs, and with excessive use of glucocorticoids, an abnormal redistribution of fat can occur.
4. Naturally occurring glucocorticoids, which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.
5. Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune response to diverse stimuli.
6. Triamcinolone Acetonide is a synthetic anti-inflammatory corticosteroid. It is intended primarily for depot intramuscular injection, but may also be used for local injection.

Pharmacokinetic:

Following a single intramuscular dose of triamcinolone acetonide 60 to 100mg, adrenal suppression occurs within 24 to 48 hours and then gradually correlates closely with the extended duration of therapeutic action achieved with the drug. Local injection also has a prolonged effect in the majority of patients. Improvements in motion and relief of pain and swelling may be obtained in a few hours, are frequently sustained over a period of several weeks and, in self limited disorders may be permanent.

Indications:

Rheumatoid arthritis, synovitis, allergic rhinitis, allergic asthma, allergic dermatitis, pemphigus, allergic and inflammatory ophthalmic diseases.

Dosage and administration:

Intramuscular administration:
For adults and children over 12 years of age, the suggested initial dose is 60mg, injected deeply into gluteal muscle. Dosage is usually adjusted within the range of 40 to 80mg.
For children from 6 to 12 years of age, the suggested initial dose is 40mg, 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 10mg for smaller areas and up to 40mg for larger areas have usually been sufficient to alleviate symptoms. Single injection into several joints for multiple locus involvement, up to a total of 80mg has been given without undue reactions.
Shake the vial before use to ensure a uniform suspension. To be administered by a physician.

Route of Administration:

Intramuscular, intra- articular and intrabursal administration.

Contraindications:

Absolute:
The use of corticosteroids is absolutely contraindicated in acute psychoses, ocular Herpes simplex, serious fungal or viral infections for which adequate anti-infective therapy is lacking, and in tuberculous meningitis when treated concomitantly with anti-tuberculous agents. The preparation should not be used to alleviate joint pain arising from infectious states such as gonococcal or tuberculous arthritis.
Relative:
Myasthenia gravis, metastatic carcinoma, diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, chronic nephritis, hypertension, thromboembolic tendencies, osteoporosis, diabetes mellitus, psychotic tendencies, and acute or chronic infections, especially chickenpox and vaccinia, as well as other exanthematous disease and fungal disease.

Precautions:

1. Because it is a suspension, the preparation should not be administered intravenously.
   Strict aseptic technique is mandatory.
2. During prolonged therapy, a liberal protein intake is essential for counteracting the tendency to gradual weight loss sometimes associated with negative nitrogen balance, wasting and weakness of skeletal muscles.
3. Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy should be carefully observed.
4. Corticosteroids may mask some signs of infections, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. If an infection occurs during corticosteroid therapy, it should be promptly controlled by suitable antimicrobial therapy.
5. Concomitant use with non-steroidal anti-inflammatory drug may increase the risk of developing peptic ulcer and gastrointestinal haemorrhage.
6. Triamcinolone may antagonize neuromuscular blockade caused by pancuronium.
7. The diabetogenic effect of Triamcinolone will impair blood glucose control with insulin and oral hypoglycaemic agents.
8. Intramuscular injection of Triamcinolone may reduce the steady-state plasma concentration of salicylate.

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9. 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.

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

Interaction with Other Medicaments:

1. Amphotericin B injection and potassium-depleting agents: Patients should be observed for hypokalaemia.
2. Anticoagulants, oral: Corticosteroids may potentiate or decrease anticoagulant action.
3. Antidiabetics: Corticosteroids may increase blood glucose; diabetic control should be monitored, especially when corticosteroids are initiated, discontinued or changed in dosage.
4. Antitubercular drugs: Isoniazid serum concentrations may be decreased.
5. Cyclosporine: Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently.
6. Digital glycosides: Co-administration may enhance the possibility of digitalis toxicity.
7. Human growth hormone (eg. somatrem): The growth-promoting effect of somatrem may be inhibited.
8. Ketoconazole: Corticosteroid clearance may be decreased, resulting in increased effects.
9. Nonsteroidal anti-inflammatory agents (NSAIDs): Corticosteroid may increase the incidence and/or severity of gastrointestinal bleeding and ulceration associated with NSAIDs.
10. Thyroid drugs: Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients.
11. 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 and Lactation:

Since adequate human reproduction studies have not been performed with corticosteroids, the use of these drugs in pregnancy, nursing mother, or women of child-bearing potential requires the possible benefits of the drug weighed against the potential hazards to the mother and the embryo, fetus, or breast-fed infant.

Side Effect(s):

Following administration by any route:
Since side effects due to systemic absorption may occur (even with local administration, and particularly with doses of 40mg or higher), patients should be watched closely for the side effects associated with any corticosteroid therapy. When adverse reactions do occur, they are usually reversible and disappear when the hormone is discontinued.

Following intra-articular administration:
Undesirable reactions have included transient pain, occasional local irritation at the injection site, local depigmentation and occasional brief increase in joint discomfort.

Following intradermal administration:
Transient local discomfort, depigmentation and local atrophy (which usually disappears unless the basic disease process is itself atrophic) has occurred.

Following intramuscular administration:
Severe pain has been reported in a few cases. Abscess formation has also occurred.

Symptoms and treatment for overdosage, and antidote(s), if any:

Symptoms of overdosage:
May produce changes in the CNS, elevated blood sugar, elevated blood pressure and oedema. Symptoms include mental confusion, anxiety, depression, GI cramping or bleeding, ecchymosis, "moon" faces and hypertension.

Treatment of overdosage:
No specific therapy. General management consists of symptomatic and supportive therapy, including gastric lavage, oxygen, I.V. fluids and maintenance of body temperature. If GI bleeding is present, treatment is the same as for peptic ulcer. Adrenal insufficiency may occur and become manifest after the effects wear off or when the patient is subjected to stress.

Shelf-life:

5 years from the date of manufacture.

Storage conditions:

Store at temperature not exceeding 30°C.
Avoid freezing and protect from light.

Product Description:

SHINCORT INJECTION 10MG; SHINCORT INJECTION 40MG/ML (1ML AMP) SHINCORT INJECTION 40MG/ML (5ML VIAL)
- A white suspension.

Packaging:

1. SHINCORT INJECTION 10MG: 5mL/vial x 10 vials.
2. SHINCORT INJECTION 40MG/ML (5ML VIAL) : 5mL/vial x 10vials
3. SHINCORT INJECTION 40MG/ML (1ML AMP) : 1mL/amp. x 100amps.

Manufacturer:
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Date of Revision: 18 June 2025