

SIVKORT INJECTION 40MG/1ML
Triamcinolone acetonide 40MG/1ML sterile suspension for injection

Description

A white suspension liquid in amber glass ampoules.

Composition

Each 1 ml injection ampoule contains 40 mg of Triamcinolone Acetonide.

Action

Triamcinolone Acetonide is a glucocorticoid steroid. Its metabolism of action is the same as other glucocorticoid steroids.

Summary of Pharmacodynamics and Pharmacokinetics

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

Intramuscular Injection: Provides an extended duration of therapeutic effect and fewer side effects of the kind associated with oral corticosteroid therapy, particularly gastrointestinal reactions such as peptic ulceration. Studies indicate that, following a single intramuscular dose of 80mg 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.

Triamcinolone acetonide may be absorbed into the systemic circulation from synovial spaces. 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 metabolic 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

Sivkort injection is indicated in the treatment of allergic state, dermatologic diseases, collagen diseases, synovitis and arthritis.

Adverse reactions/side effects

The following side effects have been selected on the basis of their potential clinical significance:

- 1) Those indicating need for medical attention:
 - Incidence less frequent:
 - Decreased or blurred vision (diabetes, cataracts)
 - Frequent urination or increased thirst (diabetes).
 - Incidence rare:
 - Skin rash (hypersensitivity reaction).
- 2) Those occurring principally during long-term use indicating need for medical attention:
 - Acne or other skin problems.
 - Back or rib pain (osteoporosis).
 - Bloody or black tarry stools (gastrointestinal bleeding).
 - Continuing stomach pain or burning (peptic ulcer, pancreatitis).

- Depression.
 - Mood or mental changes (psychic changes).
 - Increased susceptibility to infections.
 - Irregular heartbeats.
 - Muscle cramps or pains.
 - Unusual tiredness or weakness (potassium loss).
 - Menstrual problems (endocrine imbalance).
 - Moon face (Cushing's syndrome).
 - Muscle weakness (steroid myopathy).
 - Nausea and vomiting (pancreatitis).
 - Seeing halos around lights (glaucoma).
 - Swelling of feet or lower legs (sodium retention).
 - Tuberculosis reactivation.
- 3) Those indicating need for medical attention only if they continue or are bothersome:
- Incidence more frequent:
 - Indigestion.
 - Incidence less frequent:
 - False sense of well-being.
 - Increase in appetite, nervousness and restlessness.
 - Trouble in sleeping.
 - Weight gain.
- 4) Those occurring principally after medication are discontinued indicating possible adrenal suppression and the need for medical attention:
- Dizziness or fainting.
 - Low grade fever.
 - Muscle or joint pain.
 - Nausea or vomiting.
 - Prolonged loss of appetite.
 - Shortness of breath.
 - Unusual tiredness or weakness.
 - Unusual weight loss.

Precaution/warnings

- 1) Withdrawal: following prolonged therapy, withdrawal of corticosteroids may result in symptoms of the corticosteroid withdrawal syndrome including fever, myalgia, arthralgia and malaise. This may occur in patients even without evidence of adrenal insufficiency.
- 2) Regular visits to physicians to check progress during and following therapy.
- 3) Possible need sodium restriction and /or potassium supplementation during long-term therapy.
- 4) Caution in receiving vaccinations, other immunizations and skin tests.
- 5) Caution if any kind of surgery or emergency treatment is required.
- 6) Caution if serious infections or injuries occur.
- 7) Caution should be taken in lactating and pregnant women.

Contraindications

Triamcinolone Acetonide is contraindicated in patient with hypersensitive to Triamcinolone Acetonide or any.

All conventional contraindications to cortisone therapy, in particular peptic ulcer, unmanaged infections or mycosal conditions and certain viral infections, osteoarthritis of the hip.

Dosage and directions for use

20 – 80 mg administered intramuscularly per time. The dosage may be justified depending on the severity of the disease.

Shake the ampoule well before use. The precaution for rigorous asepsis should be observed before injection.

Sivkort should not be administered by the intravascular or intraspinal route neither into the SC cellular tissue nor into infected medium.

Incompatibility

Triamcinolone Acetonide should not be combined with other aqueous solutions of medicaments except with water for injection. The injection should be freshly prepared and unused portions should be discarded.

Use in pregnancy and lactation

Sivkort pregnancy class C. Sivkort is distributed into breast milk that may be harmful to breast-fed infants. It must be avoided in pregnancy and have benefit of treatment like in asthma, outweighs risk. Sivkort have risk of:

- Intra-uterine growth restriction on prolonged or repeated systemic treatment.
- Corticosteroid cover required by mother during labour and monitor closely if fluid retention.

Drug interactions

It should be care when use corticosteroid concurrently with the following medications:

- Alcohol or other anti-inflammatory medications (risk of gastrointestinal bleeding increase).
- Amphotericin B or potassium-depleting diuretics (enhance hypokalemia).
- Cardiac glycosides (enhance the possibility of arrhythmias or digitals toxicity associated with hypokalemia).
- Coumarin type anticoagulants (increase or decrease of anticoagulant effect).
- Hypoglycemics (may increase blood glucose levels).
- Phenobarbital, Phenytoin and Rifampicin (decrease corticosteroid effect).
- Salicylate (decrease plasma concentration of Salicylate and cause salicylism when corticosteroid dosage is decreased or discontinued).

Overdosage, symptoms and treatment

Since there is no special antidote, treatment of Triamcinolone Acetonide overdose or toxic reactions should be symptomatic and supportive.

Presentation

This injection is available in 1 ml ampoules

10 ampoules are packed into one folded paper box.

Storage conditions

Protect from light and store below 30⁰C Celcius. Keep out of reach of children.

Shelf-life

The injections can be used within 60 months from the date of manufacturer if kept as recommended. Discard any unused portion.

Registration number

Sivkort-MAL07xxxxxxA

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