1. NAME OF THE MEDICINAL PRODUCT

Brand Name: --
Generic Name: Triamcinolone Acetonide injection BP

Composition:
Each ml contains: -
Triamcinolone Acetonide BP ….40 MG
Benzyl Alcohol (As Preservative) BP....1 % V/V
Water for Injection BP…..QS

Pharmaceutical form: Aqeuous Suspension For Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Ingredients	Specification	Label Claim	Qty/ml (mg)	Overages	Reason for inclusion
ACTIVE						
1.	Triamcinolone Acetonide	BP	40.0 mg	40.00	--	Active
EXCIPIENTS						
2.	Benzyl Alcohol	BP	1% v/v	0.01 ml	--	Preservative
3.	Sodium Chloride	BP	--	6.50	--	Tonicity
4.	Carboxy methyl cellulose	BP	--	6.40	--	Suspending Agent
5.	Polysorbate -80	BP	--	0.4	--	Surfactant
6.	Water for injections	BP	--	q.s. to 1 ml	--	Vehicle

Where,
BP = British Pharmacopoeia

3. PHARMACEUTICAL FORM

Aqeuous Suspension For Injection

4. Clinical particulars

4.1 Therapeutic indications

Intramuscular use: Where sustained systemic corticosteroid treatment is required: Allergic states: bronchial asthma. (see section 4.2); Endocrine disorders, e.g. primary or secondary adrenocortical insufficiency. Collagen disorders, e.g. duringan exacerbation

of maintenance therapy of selected cases of SLE or acute rheumatic carditis; Dermatological diseases,e.g. pemphigus, severe dermatitis and Stevens Johnson Syndrome; Rheumatic, Gastrointestinal or Respiratorydisorders - as an adjunctive, short-term therapy; Haematological disorders, e.g. acquired (autoimmune) haemolyticanaemia; Neoplastic diseases, e.g. palliative management of leukaemia and lymphomas; Renal disease, such as acuteinterstitial nephritis, minimal change nephrotic syndrome or lupus nephritis.

4.2 Posology and method of administration

Posology

Triamcinolone Acetonide injection BP is for 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.

Method of administration

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 (1.0 ml) 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 asthma who do not respond to conventional therapy may obtain a remission of asthmatic symptoms after a single dose of 40-100 mg given when allergic symptoms appear (see section 4.4).

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 (1.0 ml injected deeply into the gluteal muscle should be scaled according to the severity of symptoms and the age and weight of the child. Triamcinolone Acetonide injection BP 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 (see section 4.4).

Triamcinolone withdrawal: In patients who have received more than physiological doses of Triamcinolone Acetonide injection BP (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 Triamcinolone Acetonide injection BP 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.

4.3 Contraindications

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

4.4Interaction with other medicinal products and other forms of interaction

Amphotericin B injection and potassium-depleting agents: Patients should be observed for hypokalaemia.
Anticholinesterases: Effects of anticholinesterase agent may be antagonised.
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 antihypertensives 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 cyclosporin when the two are used concurrently.
Digitalis glycosides: Co-administration may enhance the possibility of digitalis toxicity.
Oestrogens, including oral contraceptives: Corticosteroid 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 S CORT. 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.
CYP 3A4 inhibitors: Triamcinolone acetonide is a substrate of CYP3A4. Co-administration with strong CYP3A4 inhibitors (eg, ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with triamcinolone is not recommended because increased systemic corticosteroid adverse effects may occur. If the potential benefit of co-administration outweighs the increased risk of systemic corticosteroid side-effects, patients should be monitored for these effects. During post marketing use, there have been reports of clinically significant drug interactions in patients receiving triamcinolone acetonide and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression

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.

4.5 Pregnancy and 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 foetal 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.
Breast-feeding:
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

4.6 Effects on ability to drive and use machines

Not known

4.7 Undesirable effects

The list of undesirable effects shown below is presented by system organ class, MedDRA preferred term, and frequency. Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (≥1/10,000); Not known (cannot be estimated from the available data).

System Organ Class	Frequency	MedDRA Terms
Infections and infestations	Common	Infection
	Uncommon	Injection site abscess sterile, Infection masked, Tuberculosis,

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		Candida infection, Eye infection viral, Eye infection fungal, Rhinitis, Conjunctivitis
Immune system disorders	Uncommon	Anaphylactoid reaction Anaphylactic reaction Anaphylactoid shock
Endocrine disorders	Uncommon	Cushingoid, Adrenal suppression, Secondary adrenocortical insufficiency, Hypopituitarism
Metabolism and nutrition disorders	Uncommon	Sodium retention, Fluid retention, Alkalosis hypokalaemic, Hyperglycaemia, Diabetes mellitus inadequate control, Calcium deficiency, Increased appetite
Psychiatric disorders	Uncommon	Psychiatric symptom, Depression, Euphoric mood, Mood swings, Psychotic disorder, Personality change, Insomnia, Drug dependence, Mental disorder, Irritability, Suicidal ideation, Anxiety, Cognitive disorder
Nervous system disorders	Common	Headache
	Uncommon	Convulsion, Epilepsy, Syncope, Benign intracranial hypertension, Neuritis, Paraesthesia, Intracranial pressure increased, Dizziness
Eye disorders	Uncommon	Blindness, Cataract, Glaucoma, Exophthalmos, Corneal perforation, Papilloedema
Ear and labyrinth disorders	Uncommon	Vertigo
Cardiac disorders	Uncommon	Cardiac failure congestive, Arrhythmia
Vascular disorders	Uncommon	Hypertension, Embolism, Thrombophlebitis, Vasculitis necrotising, Hypotension, Flushing

Gastrointestinal disorders	Uncommon	Peptic ulcer, Peptic ulcer perforation,Peptic ulcer haemorrhage, Pancreatitis, Abdominal distension, Oesophagitis ulcerative, Dyspepsia
Skin and subcutaneous tissuedisorders	Uncommon	Urticaria, Rash, Skin hyperpigmentation, Skin hypopigmentation, Skin atrophy,Skin fragility, Petechiae,
		Ecchymosis, Erythema, Hyperhidrosis, Purpura, Skin striae, Hirsutism, Dermatitis acneiform, Cutaneous lupus erythematosus, Angioedema, Pruritus
Musculoskeletal connective tissue and bone disorders	Common	Arthralgia
	Uncommon	Osteoporosis, Osteonecrosis, Pathological fracture, Fracture delayed union, Musculoskeletal discomfort, Muscular weakness, Myopathy, Muscle atrophy, Growth retardation, Neuropathic arthropathy, Myalgia
Renal and urinary disorders	Uncommon	Glycosuria
Reproductive system and breast disorders	Uncommon	Menstrual irregularities, Amenorrhoea and Postmenopausal vaginal bleeding
General disorders and administration site conditions	Common	Injection site reaction
	Uncommon	Synovitis, Pain, Injection site irritation, Injection site discomfort, Fatigue, Impaired healing, Hyperthermia

Investigations	Uncommon	Blood potassium decreased, Electrocardiogram change, Carbohydrate tolerance decreased, Nitrogen balance negative, Intraocular pressure increased, Laboratory test interference, Weight decreased, Blood calcium abnormal, Protein total abnormal
Injury and poisoning	Uncommon	Spinal compression fracture

4.8 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties Pharmacotherapeutic group: glucocorticoid,

ATC code: D07XB02

Mechanism of action:

Pharmacotherapeutic group: Synthetic glucocorticoid with marked anti-inflammatory and anti-allergic actions.

Mechanism of action

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.

5.2 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 depotadministration 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 cleavageof 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.

5.3 Preclinical safety data

Not Available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol	BP
Sodium Chloride	BP
Carboxy methyl cellulose	BP
Polysorbate -80	BP
Water For injection	BP

6.2 Incompatibilities

Nil.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at temperature below 25^0C. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration orimplantation>

1 ml Triamcinolone Acetonide Injection filled in Clear glass vial plugged with grey bromo butyl rubber plug with flip-off seal, is packed in a primary Carton along with Pack insert.

6.6 Special precautions for disposal <and other handling>

No special requirements

7. <APPLICANT >

Malven Medics Int'l Co.Ltd.

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