1. Name of the medicinal Product

TRIAMACORT (Triamcinolone Acetonide Injection BP 40 mg/ml) solution for injection

2. Qualitative and Quantitative Composition

Triamcinolone Acetonide BP 40 mg/ml
Excipient(s) with known effect: Benzyl alcohol

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Suspension for Injection

A white to off white colour suspension.

4. Clinical Particulars

4.1. Therapeutic Indications

It is used for the treatment of joint pain, swelling and stiffness in inflammatory disorders such as rheumatoid arthritis. It is also for the treatment of various allergic disorders including asthma, blood disorders, hormone problems, rheumatic fever, and problems associated with digestive system, kidneys, lungs or skin.

4.2. Posology and Method of Administration

Route of administration:

Use only Intramuscular/Intra-articular injection. Do not used for intravenous, intradermal or intraocular. The strict aseptic precautions taken. The duration of effect is variable, subsequent doses should be given when symptoms recur and not at set intervals. It should not be physically mixed with other medicinal products.

Intra-Articular Injection (I.A): It is recommended that injections given into sheaths of short tendons, bursae, Dose: may vary from 5-10 mg, smaller joints: (0.125 - 0.25 ml), larger joints: up to 40 mg (1.0 ml), depending on the specific disease entity being treated. Single injections into several sites for multiple joint involvement, up to a total of 80 mg given without undue reactions. It should not be used in achilles tendon.

Intramuscular Injection (I.M): To avoid the danger of subcutaneous fat atrophy, it is important to ensure that deep intramuscular injection given into the gluteal site. The deltoid should not be used. Alternate sides should be used for subsequent injections.
Recommended dosage
Adults and children over 12 years: 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.
Elderly: In elderly patients, if long-term use of corticosteroids, common side effects may occur (i.e osteoporosis, diabetes, hypertension, susceptibility to infection and thinning of the skin) close supervision is required to avoid more serious consequences reactions.

Children from 6-12 years of age: Initial dose of 40 mg (1.0 ml) age and weight of the child Injected deeply into the gluteal muscle should be scaled according to the severity of symptoms. Child growth on prolonged corticosteroid therapy should be carefully monitored. Caution should be used in the event of exposure to chickenpox, measles or other communicable diseases.

Withdrawal: In patients who have received more than physiological doses of triamcinolone acetodine (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 achieved as the dose of systemic corticosteroid is reduced. Clinical assessment of disease may needed. Abrupt withdrawal of short-term systemic corticosteroid treatment is appropriate if it considered that 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 injection prescribed within one year of cessation of long-term therapy (months or years).

4.3. Contraindications

Hypersensitivity to any of the excipients. Systemic infections unless specific anti-infective therapy is employed. Administration by intravenous, intrathecal, epidural, or intraocular injection. Should not recommended in children age below six years.

4.4. Special Warnings and Special Precautions for Use

The safety and efficacy by other routes has yet to be established (intra-turbinal, subconjunctival, sub-tenons, retrobulbar and intraocular (intravitreal). Endophthalmitis, eye inflammation, increased intraocular pressure and vision loss reported. Visual disturbance may be report with systemic and topical corticosteroid use. (i.e. cataract, glaucoma or rare: central serous chorioretinopathy). Corticosteroid injection of into the nasal turbinates (blindness) and intralesional injection about the head. Individuals receiving triamcinolone acetonide injection very serious reactions reported in regardless of the route of administration.

Intra-Articular Injection: Intra-articular injection should not injected out in the presence of active infection in or near joints and unstable joints, achilles tendon. it should not be used to alleviate joint pain arising from infectious states such as gonococcal or tubercular arthritis. Patients should warn avoid over-use for long period in joints in which symptomatic benefit obtained. Patients should be care taken while it given to tendon sheaths to avoid injection into the tendon itself. Repeated injection into inflamed tendons should be avoided.

Intramuscular Injection: During long-term remedy, a liberal protein intake is essential to counteract the tendency to gradual weight loss sometimes associated with negative nitrogen balance and wasting of skeletal muscle.

The adverse effects may be minimised using the effective low dose for the least period, and by administering the daily requirement, whenever possible, as a single morning dose on alternate days. Frequently patient care is required to titrate the dose appropriately against disease activity. Patients should carry steroid treatment cards, which give clear guidance on the precautions taken to minimise risk and which provide details of prescriber, drug, dosage and the duration of treatment.

Withdrawal of corticosteroids after long-term therapy must, therefore, always gradual to avoid acute adrenal insufficiency and should tapered off over weeks or months according to the dose and duration of treatment. If corticosteroids stopped following long-term treatment, they may need to be re-introduced temporarily. Corticosteroid suppress your body's natural immune response, it should not be stop and the dose may need to be increased.
Passive immunization with varicella zoster immunoglobulin is needed by exposed non-immune patients who are receiving systemic corticosteroids or who have used them within the previous 3 months; varicella-zoster immunoglobulin should preferably be given within 3 days of exposure and not later than 10 days. Patients should be advice to avoid exposure to measles and to seek medical advice immediately if exposure occurs. Live vaccines should not be administered.

Patients/carers should also be alert and encouraged to seek medical advice if worrying or might occur potentially severe psychiatric adverse reactions (suspected: depressed mood, suicidal ideation) with systemic steroids. Immediately after dose tapering/withdrawal of systemic steroids, although such reactions reported infrequently. Patient care is required the use of systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or in their first-degree relatives.

Special Precautions:
Patient care is required the following conditions and frequent patient monitoring is necessary. Recent intestinal anastomoses, diverticulitis, thrombophlebitis, existing or history of steroid psychosis, exanthematous disease, chronic nephritis, metastatic carcinoma, osteoporosis, history of peptic ulcer. Myasthenia gravis. Latent or healed tuberculosis; in the presence of local or systemic viral infection, systemic fungal infections. All corticosteroids increase calcium excretion. Aspirin should be used cautiously in conjunction. The combination of drugs and co-treatment with CYP3A inhibitors drugs should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side effects, patients monitoring should be followed. Corticosteroid effects may be enhanced in patients with hypothyroidism and decreased in hyperthyroid patients.

Diabetes may be aggravated, necessitating a higher insulin dosage. Latent diabetes mellitus may be precipitated. Postmenopausal women: menstrual irregularities, vaginal bleeding may

occur. This possibility to female patients but should not deter appropriate investigations as indicated. Especially when in-patients receiving corticosteroids and history of drug allergies. Rarely: anaphylactoid reactions have occurred.

Caution for use: It contains benzyl alcohol, must not be given to premature babies or neonates. Benzyl Alcohol may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.

Use in Children: It is not used for children under six years.
Use in Elderly: In elderly patients, close supervision is required to avoid more serious consequences reactions.
Pregnancy: The corticosteroids to cross the placenta varies between individual drugs however, triamcinolone does cross the placenta. It should not recommended used during pregnancy.

Lactation: Lactating mothers taking high doses of systemic corticosteroids for prolonged periods may have a degree of adrenal suppression. Therefore, it should not recommended used during lactation.

4.5. Interaction with other medicinal products and other forms of interaction

Triamcinolone is known to interact with other drugs like (HIV: ritonavir, cobicistat, indinavir, nelfinavir, saquinavir) strong CYP3A4 inhibitors and also interact with other medicine aspirin, ibuprofen or other (NSAIDs) drugs, clarithromycin, itraconazole, nefazodone and telithromycin, cushing's syndrome and adrenal suppression, warfarin, oral contraceptive pill or hormone replacement therapy, ciclosporin, rifampicin, digoxin, myasthenia gravis, phenytoin, tuberculosis, diabetes, thyroid problems. Patients always consult physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

4.6. Fertility, Pregnancy and Lactation

Pregnancy: The corticosteroids to cross the placenta varies between individual drugs however, triamcinolone does cross the placenta. It should not recommended used during pregnancy.

Lactation: Lactating mothers taking high doses of systemic corticosteroids for prolonged periods may have a degree of adrenal suppression. Therefore, it should not recommended used during lactation.

4.7. Effects on ability To Drive and use Machines

No Known

4.8. Undesirable Effects

Steroids including injection can cause serious mental health problems. Adults and children; uncommon: mood changes, mental health disorders, feeling dependent on the medicine, trouble sleeping, fits or epilepsy, fainting and dizziness, and suicidal thought, feeling high (euphoria and mania) or moods go up and down, feeling anxious/ irritable, having problems sleeping, difficulty in thinking or being confused and losing your memory, feeling, seeing or hearing things. Very serious: cases of anaphylactic reactions may occurred. Swelling of the face, lips or throat, breathing difficulties, skin itching, redness, allergic reaction. Common: increased risk of infection at injection site reactions, headache and joint pain. Uncommon: changes in blood chemicals, fluid retention, heart failure, poor healing of broken bones fracture, loss of bone tissue, thin skin or, decrease in muscle mass, muscular weakness, rashes, stretch marks, bruising, sweating, flushing and large hair growth, itchy bumps, loss/ darkening of skin color indigestion, stomach pain and ulcers, perforation, bloating, increased appetite and weight loss, oesophagus, stomach bleeding, eye problems including inflammation, glaucoma and cataracts, blindness, bulging of the eye, irregular periods, vaginal bleeding, yeast infections, increased pressure in the brain, increased appetite, weight loss, less tolerance to carbohydrates, inadequately controlled diabetes mellitus, high blood sugar, pain, swelling and worsening of the pain in the injected joint, impaired healing, fever, treatment with steroids can stop the body from producing some hormones and may slow or stop children's growth, hormone production by certain glands may be increased or decreased, vertigo, high/low blood pressure, abnormal blood clots. Not known: blurred vision.

4.9. Overdose

Not Known

5. Pharmacological Properties

1. Pharmacodynamics Properties

Pharmacotherapeutic Group: Psycholeptics, other Antipsychotics

ATC Code: N05AX12

Triamcinolone acetonide is a synthetic glucocorticoid. Triamcinolone bind to the glucocorticoid receptors, which translocate into the nucleus and bind DNA (GRE) and change genetic expression both positively and negatively, synthetic glucocorticoid with marked anti-inflammatory and anti-allergic actions.

2. Pharmacokinetic Properties

Triamcinolone acetonide may be absorbed into the systemic circulation from synovial spaces, absorbed-slowly though almost completely, following depot administration by deep intramuscular; biologically active levels are achieved systemically for prolonged periods (weeks to months) and intra-articular are unlikely to occur except perhaps following treatment of large joints with high doses. Systemic effects do not ordinarily occur when the

proper techniques of administration and the suggested dosage regimens observed. 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. In common with other corticosteroids, triamcinolone is metabolised largely hepatically but also by the kidney and excreted in urine.

3. Preclinical Safety Data

Not Known

6. Pharmaceutical Particulars

6.1. List of Excipients

Sodium Carboxymethyl Cellulose Ph. Eur /USP

Sodium Chloride (Inj. Grade) BP/USP

Benzyl Alcohol BP

Polysorbate-80 (Tween-80) BP

Water for Injections BP

6.2. Incompatibilities

The injection should not be physically mixed with other medicinal products.

6.3. Shelf Life

36 months

Use the injection within 28 days after opening the container.

6.4. Special Precautions for Storage

Do not Store above 30°C. Protect from light.

6.5. Nature and Contents of Container

A white to off white colour suspension filled in 10 ml Clear Glass Vial. such 1 vial are in the Printed carton with Packing Insert.

6.6. Special precaution for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Tal. Kalol,

Dist. Gandhinagar,

Gujarat, India.

8. Marketing Authorization Number

TAN 22 HM 0410

9. Date of First Registration / Renewal of The Registration

21/09/2022

10. **Date of Revision of the Text**

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