TRIACORT 40 mg/ml injectable suspension – 3 vials of 1 ml
TRIACORT 80 mg/2ml injectable suspension- 3 vials of 2 ml

(triamcinolone acetonide)

PHARMACOTHERAPEUTIC CATEGORY
Corticosteroid

THERAPEUTIC INDICATIONS
The intramuscular administration of **TRIACORT** (injectable suspension of triamcinolone acetonide) is indicated in systemic corticosteroid therapy of morbose conditions such as allergic states (control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment), dermatosi, general arthritis and other affections of the connective tissues. The intramuscular administration is particularly useful in the aforesaid diseases when oral corticosteroid therappy is not feasible.
TRIACORT can be administered intra-articularly or intrabursally or directly in the tendon sheat and cystic tendon formations. These routes of administration allow to effect a valid short term local therapy of pain, of the swelling and articular rigidity caused by traumatic or rheumatoid arthritis, osteoarthritis, synovitis, bursitis and tenositis.
In the treatment of the general arthritis diseases, triamcinolone acetonide given intra-articularly is intended to support other conventional therapeutic measures. Morbous processes of localised character such as the traumatic arthritis or bursitis, may represent typical indications for instituting intra-articular administration.

CONTRAINDICATIONS
Hypersensitivity to active ingredient or inactive ingredients.
Corticosteroids are generally contraindicated in patients with systemic infections and in children under two years. The intramuscular administration of corticosteroids is contraindicated in the presence of thrombocytopenia, idiopathic purpura.

PRECAUTIONS
A state of secondary adrenal insufficiency may occur after treatment with corticosteroids and may persist for months after discontinuation of therapy. So in all conditions of stress (such as trauma, surgery or serious illness) which is manifest in this period, hormone therapy should be resumed. Since the secretion of mineralcorticoid may be compromised, sodium chloride and / or mineralcorticoid should be given in combination.
Patients suffering from hypothyroidism or from liver cirrhosis, the response to corticosteroids may be increased.
Caution in patients with ocular herpes simplex because of the possibility of a corneal perforation is recommended.
Psychic derangement may appear when corticosteroids are used, such as euphoria, insomnia, changes in mood and personality, and severe depression or symptoms of genuine psychosis. A pre-existing emotional instability or psychotic tendencies may be aggravated by corticosteroids. The use of antidepressant drugs do not relieve these problems and can exacerbate mental disorders induced by corticosteroid therapy.
Corticosteroids should be used with caution in patients with nonspecific ulcerative colitis if there is a probability of impending perforation, abscess, or other pyogenic infection. Corticosteroids should also be used cautiously in patients with diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, and

osteoporosis, acute glomerulonephritis, vaccinia, varicella, exanthema, Cushing's syndrome, antibiotic-resistant infections, diabetes mellitus, congestive heart failure, chronic nephritis, thromboembolitic tendencies, thrombophlebitis, convulsive disorders, metastatic carcinoma and myasthenia gravis.
Although TRIACORT can improve the symptoms of inflammation, it is necessary to establish the cause and treat it.
The intra-articular administration of a corticosteroid may produce systemic effects as well as local effects. The accidental injection of the suspension in the periarticular soft tissues can cause systemic effects and is the most frequent cause of treatment failure at local level.
Patients who undergo the intra-articular treatment should not put excessive stress on the joints which the symptomatological improvement has been obtained on or otherwise an increase in the deterioration of the articulation may occur.
At the intra-articular administration the over-distention of the articular capsule and the effusion of steroid along the path of the needle should both be avoided, as subcutaneous atrophy may occur.
Avoid injecting the preparation in unstable joints. In some cases, repeated intra-articular injections may themselves cause instability of the articulation. In some particular cases, especially after repeated injection, a diographic examination is recommended.
The intra-articular injection rarely causes discomfort articulation. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of a septic arthritis. If these complications should appear, and the diagnosis of septic arthritis is confirmed, administration of **triamcinolone acetonide** should be stopped and antimicrobial therapy should be instituted immediately and continued for 7 to 10 days after all evidence of infection has disappeared. Appropriate examination of any joint fluid present is necessary to exclude a septic process.
Local injection of a steroid into a previously infected joint is to be avoided.
Repeated injections in inflamed tendons were followed by rupture of the tendon itself, and therefore this practice should be avoided.
Edema may occur in the presence of renal dysfunction with an index of reduced glomerular filtration.
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.
Menstrual irregularities may occur, and this possibility should be mentioned to female patients past menarche.
In peptic ulcer, recurrence may be asymptomatic until perforation or haemorrhage occurs.
Long-term adrenocorticoid therapy may evoke hyperacidity or peptic ulcer: therefore, as a prophylactic measure, an ulcer regimen and the administration of an antacid are highly recommended.
Continued supervision of the patient after termination of **triamcinolone acetonide** therapy is essential since there may be a sudden reappearance of severe manifestations of the disease for which the patient was treated

Use in children
Exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates, and an increased incidence of kernicterus, particularly in small preterm infants. There have been rare reports of deaths, primarily in preterm infants, associated with exposure to excessive amounts of benzyl alcohol (See Special Warnings)

TRIACORT is not recommended in children younger than 6 years.
Children subjected to prolonged corticosteroid therapy should be carefully monitored in terms of growth and development since corticosteroids can suppress growth.

Should be used cautiously in case of exposure to chickenpox, measles or other infectious diseases
Children should not be vaccinated or immunised while on corticosteroid therapy. Corticosteroids may also affect endogenous steroid production.

USE IN THE ELDERLY: The common adverse effects of systemic corticosteroids such as osteoporosis or hypertension may be associated with more serious consequences in old age. Close clinical supervision is recommended.

INTERACTIONS
Amphotericin B injection and potassium-depleting agents: Patients should be observed for hypokalemia.
Anticholinesterases: Effects of the antiholinesterase agent may be antagonised.
Anticoagulants, oral: Corticosteroids may potentiate or decrease anticoagulant action. Patients receiving oral anticoagulants and corticosteroids should be closely monitored.
Antidiabetics: Corticosteroids may increase blood glucose; diabetic control should be monitored, especially when corticosteroids are initiated, discontinued, or changed in dosage.
Antitubercular drugs: Isoniazid serum concentrations may be decreased.
Cyclosporine: Monitor for evidence of increased toxicity of cyclosporine when the two are used concurrently.
Digitalis glycosides: Co-administration may enhance the possibility of digitalis toxicity.
Estrogens, including oral contraceptives: Corticosteroid half-life and concentration may be increased and clearance decreased.
Hepatic Enzyme Inducers (eg. Barbiturates, phenytoin, carbamazepine, rifampin): There may be increased metabolic clearance of Triamcinolone Acetonide. Patients should be carefully observed for possible diminished effect of steroid, and the dosage of corticosteroids should be adjusted accordingly.
Human growth hormone (eg. Somatrem): The growth-promoting effect of somatrem may be inhibited.
Ketoconazole: Corticosteroid clearance may be decreased, resulting in increased effects.
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 hypoprothrombinemia.
Thyroid drugs: metabolic clearance of adrenocorticoids is decreased in hyperthyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in adrenocorticoid drugs.
Vaccines: Neurological complications and lack of antibody response may occur when patients taking corticosteroids are vaccinated.

SPECIAL WARNINGS
This product contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with serious adverse events and death, particularly in pediatric patients. The "gasping syndrome" has been associated with benzyl alcohol. Although normal therapeutic doses of this product deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol

at which toxicity may occur is not known. Premature and low-birth-weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity.
For the presence of benzyl alcohol, this product is not recommended in children under two years .
The product should not be administered intravenously since in a form of suspension.
No studies are available to demonstrate the safe use of **TRIACORT** with intraturbinal (turbinates), subconjunctival, subtendineal, retrobulbar and intraocular (intravitreal) administration. Endophthalmitis, eye inflammation, increased intraocular pressure and visual disturbances including vision loss have been reported with intravitreal administration. Several instances of blindness have been reported following injection of corticosteroid suspensions into the nasal turbinates and intralesional head injection. Administration of TRIACORT (Triamcinolone Acetonide injectable suspension) by any of these routes is not recommended.
TRIACORT is a preparation for prolonged action and is not recommended in acute situations.
To avoid adrenal insufficiency induced by medication, a support dose is recommended in situation of stress (trauma, surgery or severe illness) both during the treatment with **TRIACORT** and the successive year.
Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections.
Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when they are used in large doses: dietary salt restriction and potassium supplementation may be necessary (see Precautions). All corticosteroids increase calcium excretion.
Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. In addition, patients who are on immunosuppressant drugs including corticosteroids are more susceptible to infections than those not taking these drugs. Moreover, chickenpox and measles can have a more serious or even fatal course in patients on corticosteroids. In such children, or adults receiving corticosteroids who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox or herpes zoster develops, treatment with antiviral agents may be considered. Similarly, corticosteroids should be used with great caution in patients with Strongyloides (threadworm) infestation because corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicaemia.

Patients should not be vaccinated against smallpox while on corticosteroid therapy. Other immunisation procedures should not be undertaken in patients who are on corticosteroids, especially on high dose because of possible hazards of neurological complications and a lack of antibody response.
The use of **triamcinolone acetonide** in patients with active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary since reactivation of the disease may occur. During prolonged corticosteroid therapy these patients should receive chemoprophylaxis.
Because rare instances of anaphylactoid reactions have occurred in patients receiving parenteral corticosteroid therapy, appropriate precautionary measures should be taken

prior to administration, especially when the patient has a history of allergy to any medication.
It is recommended that intramuscular injection is carried out in deep since local atrophy can be checked. The buttocks region is to be preferred to the deltoid because a higher incidence of local atrophy is being experienced in this area.

Pregnancy and Lactation
Many corticosteroids have been shown to be teratogenic in laboratory animals at low doses. Since adequate human reproduction studies have not been done with corticosteroids, the use of these medications in pregnancy, nursing mothers, or women of child-bearing potential requires that the possible benefits of the medication be weighed against the potential hazards to the mother and the embryo, foetus, or nursing infant. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

EFFECTS ON ABILITY TO DRIVE AND USE OF MACHINES
There have been no studies on the ability to drive and use machines. However, given the possible occurrence of side effects dependent on the central nervous system (es dizziness), it's necessary to inform the patient of this possibility.

USE OF THE DRUG IN SPORT: THE USE OF DRUG WITHOUT THERAPEUTIC NECESSITY CONSTITUTES DOPING AND CAN DETERMINE HOWEVER POSITIVE RESULT TO THE ANTI-DOPING TESTS.

POSOLOGY AND METHOD OF ADMINISTRATION
The initial dose of triamcinolone acetonide may vary from 2.5 to 60 mg / day according to the specific disease to be treated.
In less severe cases, lower doses may be sufficient while in other patients high initial doses may be required. Generally, the amount of drug administered parenterally varies from one third to half the dose administered orally every 12 hours. In cases which may endanger the life of the patient, dosages may be more justified.
The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, the treatment should be discontinued and the patient transferred to other appropriate therapy.
IT SHOULD BE EMPHASISED THAT DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALISED ON THE BASIS OF THE DISEASE UNDER TREATMENT AND THE RESPONSE OF THE PATIENT.
It is recommended to use the minimum dose for the disease in question.
After a favourable response is noted, the proper maintenance dosage should be determined by decreasing the initial dosage in small increments at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. It should be kept in mind that constant monitoring is needed in regard to medication dosage.
If after long-term therapy the medication is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

POSOLOGY

Systemic administration:
For adults and children above 12 years: the recommended initial dose is 60 mg.
The usual dosage ranges from 40mg to 80 mg and must be individualised according to the severity of the disease and response of the patient. In same cases the symptomatology may

be well controlled with a dosage of 20mg or even less. Patients affected by pollenosis or pollen asthma having no response to the desensibilising therapy and other conventional therapies may obtain a remission of symptoms for entire pollen season receiving a single injection of 40-100mg.

For children 8-12 years: the recommended initial dosage is 40 mg, although the dosage should be governed by the severity of the condition rather than by strict adherence to the ration indicated by age or body weight.

Since the duration of effect of TRIACORT is variable the successive dosage of the drug should be administered only after re-appearing of symptoms and not at pre-established time intervals.

Newborn or premature infants: this preparation contains benzyl alcohol. It's not for use in newborn or premature infants (see "Use in children").

Local administration:

For intra-articular or intrabursal administration or direct administration in the tendon sheats:

Very often only a single local dose of triamcinolone acetonide is sufficient to induce the complete remission of symptomatology

The initial dose: 2.5–5 mg for the smaller joints and, up from 5 to 15 mg for larger joints, depending on the specific disease entity being treated. In adults, doses until to 10 mg for smaller joints and up to 40 mg for larger joints are sufficient. Single injections into several joints for multiple locus involvement, up a total of 80 mg have been given without undue reactions.

METHOD OF ADMINISTRATION

Strict aseptic technique is mandatory. Shake the vial before use to ensure a uniform suspension. Prior to withdrawal, inspect suspension for clumping or granular appearance (agglomeration). An agglomerated product results from exposure to freezing temperatures and should not be used. After withdrawal, inject without delay to prevent settling in the syringe. Careful technique should be employed to avoid the possibility of entering a blood vessel or introducing infection.

Intramuscular use: the injection should be profound and given in the region of gluteus muscles. Intramuscular distribution should be assured. In adults a 4 cm long syringe needle is recommended, in obese subjects the needle should be even longer. Alternate the injection site at each successive administration.

Local administration: in case of substantial endoarticular effusion, agrees practice prior to the aspiration of synovial fluid, but without reaching the complete emptying of the collection, this measure helps to facilitate the remission of symptoms, while avoiding excessive dilution of the steroid injected in situ. Then proceed to the intra-articular administration in accordance with the technical standards required for injection in articular cavity.

With intra-articular or intrabursal administration, and with injection of TRIACORT into tendon sheaths, the use of a local anaesthetic may often be desirable.

When a local anaesthetic is used its package insert should be read with care and all the precautions connected with its use should be observed. It should be injected into the surrounding soft tissues prior to the injection of the corticosteroid. A small amount of the anaesthetic solution may be instilled into the joint.

In treating acute nonspecific tenosynovitis, care should be taken to ensure that the injection of the corticosteroid is made into the tendon sheath rather than the tendon substance. Epicondylitis (tennis elbow) may be treated by infiltrating the preparation into the area of the greatest tenderness.

Do not use TRIACORT with intravenous, intradermal, intratendineal, intranasal (turbinates), subconjunctival, retrobulbar or intravitreal (intraocular) administration (See "Special warnings").

OVERDOSAGE

Chronic: The symptoms of overdosage may be the following: confusion, anxiety, depression, cramps or gastrointestinal hemorrhage, ecchymosis, and hypertension. Following prolonged therapy, a sudden withdrawal of the treatment may provoke supprarenal insufficiency. It could be verified in stress condition too. Development of Cushingoid state may be observed following the therapy prolonged with different dosages.

Acute: There is no specific treatment in case of overdosage with corticosteroids. In any case the support therapy should be instituted and in the condition of gastrointestinal hemorrhage the intervention should be the same as in peptic ulcer.

UNDESIRABLE EFFECTS

Following Administration by Any Route:

General: Anaphylactoid reactions; aggravation or masking of infections.

Cardiovascular: Hypertension, syncope, congestive heart failure, arrhythmias, necrotising angiitis, thromboembolism, thrombophlebitis.

Fluid and electrolyte disturbances: Sodium retention, fluid retention associated with hypertension or congestive heart failure in susceptible patients, potassium loss, cardiac arrhythmias or ECG changes due to potassium deficiency, and hypokalemic alkalosis.

Musculoskeletal: Muscle weakness, fatigue, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, delayed healing of fractures, aseptic necrosis of femoral and humeral heads, pathologic fractures of long bones and spontaneous fractures.

Gastrointestinal: Peptic ulcer with possible subsequent perforation and haemorrhage, pancreatitis, abdominal distension and ulcerative oesophagitis.

Dermatological: Impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, purpura, striae, hirsutism, acneiform eruptions, lupus erythematous-like lesions and suppressed reactions to skin tests.

Neurological: Convulsions, increased intracranial pressure with papilloedema (pseudo-tumour cerebri) usually after treatment, vertigo, headache, neuritis or paraesthesias, and aggravation of pre-existing psychiatric conditions.

Endocrine: Menstrual irregularities, development of the cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g. trauma, surgery or illness) decreased carbohydrate tolerance, manifestations of latent diabetes mellitus and increased requirements for insulin or oral hypoglycaemic agents in diabetics.

Ophthalmic: Posterior subcapsular cataracts, increased intraocular pressure, glaucoma and exophthalmos.

Metabolic: Hyperglycaemia, glycosuria and negative nitrogen balance due to protein catabolism.

Following Intra-articular Administration:

Undesirable reactions have included post injection flare, transient pain, occasional irritation at the injection site, sterile abscess formation, hyper- and

hypopigmentation, charcot-like arthropathy and occasional brief increase in joint discomfort.

Following Intradermal Administration:
Rare instances of blindness associated with intralesional therapy around the face and head, transient local discomfort, sterile abscesses, hyper- and hypopigmentation, and subcutaneous and cutaneous atrophy (which usually disappears, unless the basic disease process is itself atrophic) have occurred.

KEEP OUT OF THE REACH AND OF THE SIGHT OF CHILDREN

ATTENTION: DO NOT USE THE PRODUCT AFTER EXPIRY DATE INDICATED ON THE BOX AND AVOID FREEZING

COMPOSITION
Each vial of 40mg/ml of injectable suspension of **TRIACORT** contains: ACTIVE SUBSTANCE: Triamcinolone acetonide 40.0 mg; EXCIPIENTS: Carmellose sodium 7.5 mg; Sodium chloride 6.60 mg; Polysorbate 80 0.40 mg; Benzyl alcohol 9.00 mg; Water for injection q.s. to 1.0 ml.

Each vial of 80mg/2ml of injectable suspension of **TRIACORT** contains: ACTIVE SUBSTANCE: Triamcinolone acetonide 80.0 mg; EXCIPIENTS: Caramellose sodium 15.0 mg; Sodium chloride 13.2 mg; Polysorbate 80 0.80 mg; Benzyl alcohol 18.0 mg; Water for injection q.s. to 2.0 ml.

PHARMACEUTICAL FORM AND CONTENT
Injectable suspension for intramuscular or intra-articular administration.
Package of 40mg/ml injectable suspension contains 3 vials of 1 ml
Package of 80mg/2ml injectable suspension contains 3 vials of 2 ml

MARKETING AUTHORISATION HOLDER:
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