Patient Information Leaflet

TRIACORT 40 mg/ml suspension for injection
TRIACORT 80 mg/2ml suspension for injection

(triamcinolone acetonide)

PHARMACOTHERAPEUTIC CATEGORY
Systemic Corticosteroid

THERAPEUTIC INDICATIONS
Intramuscular administration of TRIACORT (Triamcinolone Acetonide suspension for injection) is indicated in a systemic corticosteroid therapy of morbose processes such as allergic syndromes (control of severe or incapacitating allergic conditions when conventional treatment is not feasible), dermatosis, general rheumatoid arthritis and other affections of the connective tissues. Intramuscular administration is particularly recommended in the aforesaid diseases when oral corticosteroid therapy is not feasible.
TRIACORT may also be given by intra-articular or intrabursal route or directly into the tendon sheaths and cystic tendon formations. Such routes of administration allow to perform an efficacious local short-term therapy of pain, of swelling, and articular rigidity caused by traumatic or rheumatoid arthritis, osteoarthritis, synovitis, bursitis and tenositis.
In the treatment of general arthritis diseases, triamcinolone acetonide given by intra-articular injection is intended to support other conventional therapeutic measures. Localised morbose processes such as traumatic arthritis or bursitis represent typical indications when only intra-articular therapy should be instituted.

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

PRECAUTIONS FOR USE
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) manifested during the treatment, hormone therapy should be re-instituted. Considering that the secretion of mineralocorticoids may be compromised, sodium chloride and/or mineralocorticoids should be given concomitantly.
In patients affected by hypothyroidism or liver cirrhosis, the response to corticosteroids may be increased. Caution in patients with ocular herpes simplex is recommended because corneal perforation may likely occur.
Psychic alterations may appear when corticosteroids are used, such as euphoria, insomnia, alteration of humour and personality, severe depression or symptoms of real psychosis. A pre-existing emotional instability or psychotic tendencies may get worse by corticosteroids.
The use of antidepressant drugs does not relieve these problems and can exacerbate mental disorders induced by corticosteroid therapy.
Corticosteroids should be used with caution in patients with non-specific 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, acute glomerulonephritis, chronic nephritis, hypertension, congestive heart failure, thrombophlebitis, thromboembolic tendencies, osteoporosis, rash, 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 give rise to both systemic and local effects. The accidental injection of the suspension in the periarticular soft tissues may cause systemic effects. It represents the most frequent cause of the local treatment failure. Patients who undergo the intra-articular treatment should not exercise an excessive stress on the symptomatically improved joints otherwise the articulation deterioration increase may be observed.
With intra-articular administration, the over-distention of the articular capsule and the injecting of steroid longwise the needle path should both be avoided, as subcutaneous atrophy may occur. Avoid injecting the preparation in unstable joints. In some cases, repeated intra-articular injection may itself cause instability of the articulation. In some particular cases, especially after repeated injection, a radiographic examination is recommended.
Intra-articular injection rarely causes articulation discomfort. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise indicate an evident arise of a septic arthritis. If these complications

should appear, administration of triamcinolone acetonide should be discontinued and antimicrobial therapy immediately instituted and continued for 7 to 10 days after any evidence of infection has disappeared. Appropriate examination of any joint fluid observed 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 should be avoided.
Oedema may occur in the presence of renal dysfunction with a glomerular filtration rate reduced.
During prolonged therapy, a sufficient protein intake is essential to reduce the tendency of gradual weight loss sometimes associated with a negative nitrogen balance, wasting and weakness of skeletal muscles.
Menstrual irregularities may occur in women treated with corticosteroids.
In peptic ulcer, recurrence may be asymptomatic until perforation or haemorrhage occurs.
Long-term adrenocorticoid therapy may cause hyperacidity or peptic ulcer so that, as a prophylactic measure, the administration of an antacid is highly recommended.
Continued supervision of the patient after termination of triamcinolone acetonide therapy is essential for a likely reappearance of severe manifestations of the disease which the patient has been treated for.

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, particularly in preterm infants, associated with exposure to excessive quantity of benzyl alcohol (see Special Warnings).

TRIACORT is not recommended in children under 6 years.
Children undergoing prolonged corticosteroid therapy should be carefully monitored in terms of growth and development since corticosteroids can suppress growth.
TRIACORT should be used with caution 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 monitoring is recommended.

Menstrual irregularities may be experienced. In post-menopausal women, vaginal bleeding has been observed. The female patients must be informed of the risk and appropriate tests are recommended to be done.

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 used concomitantly.
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): An increased metabolic clearance of Triamcinolone Acetonide is observed. Such patients should be carefully monitored and the corticosteroids dosage adjustment may be needed.
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 neuromuscular blocking action may enhance.
Nonsteroidal anti-inflammatory agents (NSAIDS): Corticosteroids may increase the incidence and/or severity of GI bleeding and ulceration associated with NSAIDS. Also, corticosteroids may reduce the salicylate serum levels and consequently decrease their efficiency. On the contrary, discontinuing corticosteroids during high-dose salicylate therapy may result in salicylate toxicity. Aspirin associated with corticosteroids should be used with caution in patients with hypoprothrombinemia.

Thyroid drugs: Metabolic clearance of adrenocorticoids is decreased in hyperthyroid patients and increased in hyperthyroid patients. The dosage of corticosteroids should be balanced if any changes of the thyroid status should occur.
Vaccines: Neurological complications and lack of antibody response may occur when patients taking corticosteroids are vaccinated.
Tell your doctor or pharmacist if you have recently taken any other medicines including those without medical prescription.

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 release the quantities 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 doses, may easily develop toxicity.
For the presence of benzyl alcohol, this product is not recommended in children under two years of age.
Being a suspension, the drug should not be administered intravenously.
No studies are available to demonstrate the safe use of TRIACORT with intranasal (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 head lesions. Administration of TRIACORT (Triamcinolone Acetonide injectable suspension) by any of these routes is neither recommended nor indicated.
TRIACORT should not be given either epidurally or intrathecally. Cases of serious adverse effects have been associated with epidural or intrathecal administration.
Cases of severe anaphylactic reactions and anaphylactic shock, including death, have been reported in subjects who an injection of triamcinolone acetonide has been given to, regardless of the route of administration.
TRIACORT is a preparation with prolonged action and is not recommended in acute states. To avoid adrenal insufficiency induced by the drug, a support dose is recommended in situation of stress (trauma, surgery or severe illness) both during the treatment with TRIACORT and the year after.
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 due to fungi or viruses.
Average and large doses of hydrocortisone or cortisone may 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 these are used in large doses: dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion that can further be associated to or worsen a pre-existing osteoporosis.
Corticosteroids may mask some signs of infection, and new infections may appear during their use.
There may be a decreased resistance and inability to localize a site of injection 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 may 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 limited to the cases of fulminating or disseminated tuberculosis in which corticosteroid is used for the management of the disease, in association with an appropriate anti-tuberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary since reappearance of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.
Considering that anaphylactoid reactions may rarely occur 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 drug.

A deep intramuscular injection is recommended to avoid local atrophy. The gluteal area is preferable to that of deltoid because a higher incidence of local atrophy is being observed in the latter 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 drugs in pregnancy, nursing mothers, or women of child-bearing potential requires that the possible benefits of the drug must be evaluated against the potential hazards to the mother and 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.
Ask your doctor or pharmacist for advice before using any medicine.

Effects on ability to drive and use of machines

Patient must be properly informed of side effects which may likely occur, affecting the central nervous system (such as vertigo).
USE OF THE DRUG IN SPORT: THE USE OF DRUG WITHOUT THERAPEUTIC NECESSITY CONSTITUTES DOPING AND CAN HOWEVER DETERMINE POSITIVE RESULT TO THE ANTI-DOPING TESTS.

POSOLOGY AND METHOD OF ADMINISTRATION

General:
The initial dose of triamcinolone acetonide may vary from 2.5 to 60 mg/day according to the disease to treat.
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 a one third to a half the dose administered orally every 12 hours. Use of higher doses is justified when life is on risk.
The initial dose 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 with TRIACORT should be gradually discontinued and the patient should undergo another therapy.
THE DOSAGE REQUIREMENTS ARE VARIABLE AND ARE ESTABLISHED ON THE BASIS OF THE DISEASE TO TREAT AND THE PATIENT RESPONSE.
It is recommended to use the lowest efficacious dose for the disease to treat.
When a favourable response is noted, the proper maintenance dose should be determined by decreasing the initial dose gradually and at appropriate time intervals until the lowest efficacious dose that will maintain an adequate clinical response is reached.
If after a long-term therapy the treatment should be interrupted, the withdrawal should be gradual.

Dosage

Systemic administration:

For adults and children above 12 years: The recommended initial dose is 60 mg.
A deep intramuscular injection in the gluteal area is recommended. If injection is not properly given, the subcutaneous fat atrophy may occur.
The usual dosage ranges from 40mg to 80 mg and is established according to the severity of the disease and response of the patient. In some cases, the symptomatology may be well controlled with a dosage of 20mg or even less. Patients suffering from pollinosis or asthma due to pollen who do not respond to either desensitizing therapy or other conventional therapies, can achieve remission of symptoms throughout the entire pollen season with a single injection of 40-100 mg.
Children from 6 to 12 years of age: The recommended initial dosage is 40 mg. However, the dosage should be defined by the severity of the symptoms rather than by a strict adherence to the age and body weight of the child.
Newborn or prematures: This product contains benzyl alcohol and is not recommended in newborns or prematures (see Precautions for Use – Use in children- and Special Warnings).

Local administration:

For intra-articular or intrabursal administration or direct administration in the tendon sheats: A single dose of triamcinolone acetonide is almost always sufficient, however, more than one dose may be needed to induce a complete remission of the symptomatology.
The initial dose: 2.5–5 mg for small joints and up from 5 to 15 mg for large joints, depending on the specific disease entity being treated. In adults, doses up to 10 mg for small joints and up to 40 mg for large joints are sufficient. Single injections of doses up to a total of 80 mg have been proved to be safe.

Method of administration

General:
Strict aseptic technique is required. Before use, shake the vial well to ensure that the suspension is uniform and without agglomerates. Exposure to low temperatures results in agglomeration and if such the case the product should not be used. After withdrawal, inject immediately to avoid the drug depositing in the syringe. Use all precautions to avoid the risk of infection or the needle to penetrate a blood vessel.

Systemically: The injection should be profound and given in the gluteus muscles area. In adults, a 4 cm long needle is recommended. In obese subjects, a longer needle may be required. Change the injection site at each successive administration.
Localy: In case of substantial endoarticular effusion, preventive aspiration of synovial fluid should be done ensuring that the fluid has not been completely aspirated. This measure helps facilitate the remission of symptoms avoiding excessive dilution of the steroid injected in situ. The intra-articular administration is performed following the procedure 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 recommended. A particular attention must be paid to this type of injection, especially if effected in the deltoid area and in the tendon sheaths, to avoid the injection of the suspension into the surrounding tissue since this can lead to the tissue atrophy.
In the treatment of acute nonspecific tenosynovitis, care should be taken to ensure that the injection of the corticosteroid is made inside the sheath rather than in the tendon. Epicondylitis may be treated by infiltrating the preparation into the area of maximum softness.
TRIACORT is not for intravenous, intradermal, subtendineal, intranasal (turbinates), subconjunctival, retrobulbar, intravitreal (intraocular), epidural or intrathecal use. For more information, see the paragraph "Special warnings".

Overdosage
Chronic: The symptoms of overdosage may include confusion, anxiety, depression, cramps or gastrointestinal hemorrhage, ecchymosis, bruising, facies lunaris, and hypertension. Following prolonged therapy, a sudden interruption of the treatment may provoke acute adrenal insufficiency. The latter may occur even in case of stress. Development of Cushingoid state may be observed following the prolonged therapy with high doses.
Acute: There is no specific treatment for acute overdosage by corticosteroids. The support therapy should be instituted. In case of gastrointestinal haemorrhage, the measures to be used should be the same as those used for peptic ulcer.
If you have any further question about Triacort, ask your doctor or pharmacist.

UNDESIRABLE EFFECTS
Like other medicines, TRIACORT may cause undesirable effects although not everybody manifests them

List of undesirable effects:
Common (may affect not more than one of 10 people)
- Infection
- Headache
- Cataracts
- Reactions at site of injection
Uncommon (may affect not more than one of 100 people):
-Sterile abscess at the injection site, masked infection
- Anaphylactoid reaction, anaphylactic reaction, anaphylactic shock
- Cushingoid state, adrenal suppression
- Sodium retention, fluid retention, hypokalemic alkalosis, hyperglycemia, diabetes mellitus, inadequate control of diabetes mellitus
- Psychiatric symptom, depression, euphoric mood, mood swings, psychotic disorder, personality change, insomnia
- Convulsions, syncope, benign intracranial hypertension, neuritis, paresthesia
- Blindness, glaucoma, exophthalmos, corneal perforation
- Vertigo
- Congestive heart insufficiency, arrhythmia
- Hypertension, embolism, thrombophlebitis, necrotizing vasculitis
- Peptic ulcer, peptic ulcer with perforation, peptic ulcer with hemorrhage, pancreatitis, abdomen distension, ulcerative esophagitis
- Urticaria, rash, cutaneous hyperpigmentation and hypopigmentation, cutaneous atrophy, cutaneous fragility, petechiae, ecchymosis, erythema, hyperhidrosis, purpura, cutaneous striae, hirsutism, acneiform dermatitis, cutaneous lupus erythematosus

- Osteoporosis, osteonecrosis, pathological fracture, delayed consolidation of fracture, musculoskeletal discomfort, muscle weakness, myopathy, muscle atrophy, growth retardation, neuropathic arthropathy
- Glycosuria
- Irregular periods, amenorrhea, postmenopausal bleeding
- Synovitis, pain, skin irritation at the site of injection, discomfort at the site of injection, fatique, incomplete healing
- Lower blood potassium level, modification of the electrocardiogram, reduced carbohydrate tolerance, negative nitrogen balance, increased intraocular pressure, interference in laboratory analyses
- Vertebral compression fracture

Not known
- Hiccups

Correct following of the instructions contained in the leaflet reduces the risk of undesirable effects.

Reporting of side effects
If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via National Reporting System at:
http://www.agenziafarmaco.gov.it/it/responsabili. By reporting side effects, you can help provide more information on the safety of this medicine.

KEEP OUT OF THE REACH OF CHILDREN

SHELF-LIFE AND STORAGE
Keep below 25°C
ATTENTION: DO NOT USE THE PRODUCT AFTER EXPIRY DATE SHOWN ON THE BOX
AVOID FREEZING

COMPOSITION
Each vial of 40mg/1ml of suspension for injection contains: ACTIVE SUBSTANCE: Triamcinolone acetonide 40.0 mg; EXCIPIENTS: Carmellose sodium, Sodium chloride, Polysorbate 80, **Benzyl alcohol**, Water for injection q.s. to 1.0 ml.

Each vial of 80mg/2ml of suspension for injection contains: ACTIVE SUBSTANCE: Triamcinolone acetonide 80.0 mg; EXCIPIENTS: Carmellose sodium, Sodium chloride, Polysorbate 80, **Benzyl alcohol**, Water for injection to 2.0 ml.

PHARMACEUTICAL FORM AND CONTENT
Suspension for injection for intramuscular and intra-articular administration.
Package of 40mg/1ml: 3 vials
Package of 80mg/2ml: 3 vials

MARKETING AUTHORISATION HOLDER:
PHARMATEX ITALIA S.R.L.
Via San Paolo, 1
20121 Milan (ITALY)

MANUFACTURER AND FINAL RELEASER:
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