

Composition:

Active ingredient: Flacort.

Excipients: tablets 6 mg and 30 mg: Lactose monohydrate, Microcrystalline cellulose, Maize starch, Magnesium stearate.

Dosage form and quantity of active ingredient per unit: Tablets 6 & 30mg.

Indications:

Endocrine: - Primary adrenal insufficiency or secondary (hydrocortisone or cortisone is the drug of first choice, given its very weak mineralocorticoid effect, deflazacort should be used only in combination with a mineralocorticoid, particularly when treating children.)
- congenital adrenal hyperplasia.

Rheumatic and collagen: Treatment of acute attacks and / or maintenance treatment of rheumatoid arthritis and psoriatic arthritis when the usual treatments have proven ineffective; rheumatic polymyalgia , rheumatic fever, lupus erythematosus, dermatomyositis, polyarteritis nodosa, temporal arteritis, Wegener's granulomatosis.

Other inflammatory: Non itchy Thyroiditis.

Dermatological: Acute , severe dermatitis as pemphigus, bullous dermatitis herpetiformis, generalized exfoliative dermatitis, erythema multiforme, erythema nodosum, severe psoriasis.

Allergies: Bronchial asthma not responding to conventional treatment.

Lung: Sarcoidosis with pulmonary infiltrates, exogenous allergic alveolitis (pneumoconiosis due to organic dusts), desquamate interstitial pneumonia.

Eye disorders: Choroiderinitis and choroiditis, iritis and iridocyclitis.

Blood: Idiopathic thrombocytopenia in adults, acquired autoimmune hemolytic anemia.

Neoplasia: Palliative treatment of acute leukemia in children as well as leukemia and lymphoma in adults.

Renal: Nephrotic syndrome (some forms).

Gastro-intestinal and liver: Ulcerative colitis, Crohn's disease, chronic aggressive hepatitis.

Dosage / Instructions:

General dosing recommendations:

Corticosteroids usually complete a basic treatment, but do not replace it.

Since the entry into action of deflazacort - like all glucocorticoids - is usually delayed (see "Properties / Effects"), Flacort should not be used as a replacement short-term treatment of severe acute states (potentially fatal), but if necessary as a supplement to such treatment. Should consult the information on these drugs.

Usual dose: The dosage may vary between 6 mg and 90 mg per day and will be determined in each case depending on the type of disorder, severity, prognosis, the likely duration of the disease or treatment, patient response and tolerance of medicine.

The drug is taken in the morning with or after breakfast, if every other day.

It should always choose the lowest effective dose; the dose reductions should be gradual. When Flacort replace treatment with another glucocorticoid it should be taken into account the equivalent doses (see "Properties / Effects").

Acute disorders: Depending on the severity of symptoms, 30 mg to 90 mg per day. It should reduce the dose as soon as possible, reducing the successive increments of 3 mg to 6 mg.

Chronic: The initial dose varies between 24 and 36 mg per day. Once symptoms are controlled, the high initial dose should be gradually (within a few days) reduced to a lower maintenance dose to double the dose limit of Cushing. For deflazacort, the minimum maintenance dose according to the indication usually ranging between 6 and 18 mg per day.

Long-term treatment: A long-term treatment with glucocorticoids should be initiated only after a cautious assessment of risks. In this case, too, should try to gradually reduce the dosage and stopping treatment as soon as possible. In all cases, we should remain alert to signs that require a dose reduction or discontinuation of medication.

In a spontaneous remission of a chronic condition, treatment should be stopped (if applicable, by reducing the dose gradually). In cases of exacerbation of existing disease and in patients subjected to unusual stress (eg surgery, severe trauma, severe infection), a transient increase in dose may however be necessary (see "Warnings and Precautions"). Do not stop a long-term treatment abruptly, but gradually, to minimize any risk of recurrence of the disease and enable the hypothalamic-pituitary axis to regain its function.

Patients on long-term treatment should carry with them an identification card and that until a year after stopping treatment. This card should include information on the disease, the dose of deflazacort, and indicate the name and telephone number of the physician.

Duration of treatment: Like other glucocorticoids, deflazacort should never be taken longer than strictly necessary.

Special Dosage:

Pediatrics: The pediatric clinical trials on the efficacy and safety of deflazacort are limited.

In infants and children, lower doses than those previously described are generally adequate, but should be adjusted to the degree of severity of illness at the age, body weight or size.

We must always give the smallest dose, if possible in a batch (see Warnings and Precautions).

Elderly: No special precautions are required beyond those normally be taken during treatment with glucocorticoid.

Renal: No special precautions are required beyond those normally be taken during treatment with glucocorticoid.

Hepatic failure, hypothyroidism: No specific studies are available. Blood levels of deflazacort may be increased. Therefore, dosage must be monitored and reduced to the minimum effective dose.

Adrenocortical insufficiency: See "Directions" Endocrine.

Stressful situations: See paragraphs "Long-term treatment" and "warnings and precautions".

Contraindications:

Hypersensitivity to deflazacort or other ingredients of the product.

A long-term Flacort, apart from emergency treatment with a glucocorticoid appropriate contraindicated in the presence of the following diseases: peptic ulcer, uncontrollable infections (viral, bacterial or fungal) eye infections, herpes simplex, polio (with the exception of forms-bulbar encephalitis), amoebiasis, lymphoma after BCG vaccination, almost 8 weeks before until 2 weeks after vaccination, severe hypertension, narrow angle glaucoma or open, severe heart failure, renal failure, acute glomerulonephritis, severe osteoporosis, psychiatric history, pregnancy, lactation.

Warnings and Precautions:

The possible complications of glucocorticoid treatment depend on the dose used and duration of treatment. The clinical pictures below generally require special caution before the introduction of glucocorticoid treatment:

- **Heart disease or heart failure:** (with the exception of acute rheumatic heart disease), recent myocardial infarction, hypertension, thromboembolic disorders, osteoporosis. Glucocorticoids can cause fluid retention, or increased excretion of potassium. A diet low in salt and potassium substitution may be necessary.

- **Gastritis or esophagitis,** diverticulitis, ulcerative colitis with perforation or threat of pyogenic infection, recent intestinal anastomoses.

- **Emotional instability or tendency to psychotic reactions to the trend;** epilepsy.

- **Glaucoma.**

- **Hypothyroidism and liver cirrhosis,** in effect, these conditions could enhance the action of glucocorticoids.

- In a long-term treatment, especially in cases of diabetes mellitus, glucose metabolism should be monitored regularly because glucose tolerance may be decreased and increased the dose of antidiabetic be necessary.

- During a long-term treatment, the intraocular pressure should be measured regularly, in fact, it may increase during treatment. This increase is usually reversible, but during a prolonged use of corticosteroids, a subcapsular cataracts or glaucoma with irreversible damage to the optic nerve can occur, and the appearance of secondary fungal eye infections can be viral or favored.

- In patients who suffered myocardial infarction, there is a risk of left ventricular rupture.

- At the onset of gastric or intercurrent infectious diseases, should warn the physician.

- **Potassium** - wasting diuretics may enhance the effect of glucocorticoids kaliuretic. Therefore, patients taking diuretics will be carefully monitored for possible hypokalemia. This is particularly important in patients receiving concurrent cardiac glycosides, because hypokalemia induced by corticosteroids increases the toxicity of these drugs. Potassium substitution may be necessary.

- If concomitant administration of acetylsalicylic acid in patients with hypoprothrombinemia, increases the risk of bleeding.

- In cases of long-term treatment combining glucocorticoids and salicylates, there is increased risk of gastrointestinal bleeding and ulcers up to the perforation. Given the risk of salicylate poisoning, the dose of glucocorticoid should be reduced cautiously.

- In case of myasthenia gravis and concurrent administration of cholinesterase inhibitors, the effect of cholinesterase inhibitors and reduces the risk of a myasthenic crisis increases, therefore the administration of cholinesterase inhibitors should if possible be stopped 24 hours before that of a corticosteroid.

- In cases of acute bronchial asthma, Flacort should not be used as replacement of conventional treatment, but complement it. Glucocorticoids, however should not be taken in case of chronic uncomplicated respiratory diseases.

- Corticosteroids may mask some signs of infection, and during their use, new infections may appear. In patients with active infections, it is necessary to ensure adequate antibiotic or chemotherapy protection.

- Employment in cases of active TB should be limited to cases of fulminating or disseminated tuberculosis in whom deflazacort must necessarily be administered together with an appropriate antituberculosis therapy. When corticosteroids are indicated in patients with latent tuberculosis or tuberculin reaction positive, close monitoring is necessary because the disease can be reactivated. In case of prolonged corticosteroid therapy, patients should receive preventive therapy.

- When chickenpox occurs during treatment with systemic corticosteroids, its evolution can be severe and can, especially in children, have a fatal outcome. Chickenpox requires immediate treatment, such as acyclovir intravenously in patients at risk, preventive treatment with acyclovir or preventive immunotherapy with anti-chickenpox immunoglobulin are indicated.

- The presence of a latent amebiasis must be excluded before treatment.

- Immunizations are contraindicated for patients on corticosteroids, especially when high doses are used, since a spread of live vaccine and / or absence of immunological reaction is possible.

- Stopping corticosteroids after prolonged treatment can cause withdrawal symptoms like: fever, myalgia, arthralgia and malaise; inhibiting the release of ACTH may cause adrenocortical insufficiency, up to the atrophy of the adrenal cortex. Withdrawal symptoms may also occur in patients without adrenal insufficiency.

- Inhibition of the adrenal cortex may persist for a year or more and compromises the prognosis of patient survival in cases of stress or difficult situations (see "Dosage and method of use - Long-term treatment").

- At the appearance of Cushing's syndrome, the dose should be reduced gradually.

Caution is also needed: among postmenopausal women or elderly patients, due to the higher risk of osteoporosis. If osteoporosis occurs in these patients, treatment with glucocorticoids should be discontinued, unless otherwise vital indication.

- Children and grand children in whom it should closely monitor the growth and development throughout long-term treatment with glucocorticoids, because of the risk of premature closure of the epiphysis.

Interactions:

- A large number of interactions between glucocorticoids and other drugs are known and must be taken into account for deflazacort. The interactions described below and those listed under "Warnings and Precautions may require dose adjustment of Flacort and / or other drug (s) administered (s) simultaneously.

- Substances inducing hepatic microsomal enzymes, such as rifampicin, barbiturates and phenytoin, may accelerate the metabolism of glucocorticoids. We must therefore adjust the dosage of glucocorticoids in patients receiving maintenance therapy with glucocorticoids when such drugs are administered simultaneously or otherwise removed.

- Estrogens may cause an enhanced effect of corticosteroids in decreasing the clearance of them.

- Immunosuppressants: in case of simultaneous administration of methotrexate, a lower dose of corticosteroids may be sufficient due to a synergistic effect. Cyclosporin decreases the clearance of corticosteroids, probably through competitive inhibition of hepatic microsomal enzymes and conversely, corticosteroids can, especially when administered at high doses, increase blood levels of cyclosporin.

- Sympathomimetics: the effect and potential toxicity of certain stimulants (e.g. salbutamol) can be strengthened, and ephedrine can cause an increased clearance of plasma glucocorticoids and renal excretion of its metabolites.

- Atropine and other anticholinergic drugs may cause an additional increase of intra-ocular hypertension.

- The effect of substances not depolarizing causing neuromuscular blockage (e.g. pancuronium) is antagonized by corticosteroids.

- The effect of anxiolytics and antipsychotics may be decreased.

- The serum thyroxine (T₄) And the uptake of I¹³¹ can be reduced.

See the paragraph "Warnings and Precautions for the following interactions.

- Vaccines and immune response;

- antidiabetic and glucose tolerance;

- anti-inflammatory drugs and the risk of bleeding;

- salicylates and salicylate poisoning;

- Diuretics promote the elimination of potassium and hypokalemia and / or digitalis poisoning.

- The cholinesterase inhibitors in myasthenia gravis.

Pregnancy / Lactation:

Pregnancy: There is no sufficient data in pregnant women.

Studies in animals with glucocorticoids showed teratogenic dose-dependent in rats and rabbits. Whether deflazacort crosses the placental barrier, but this is the case with other glucocorticoids. Therefore, disorders of intrauterine growth cannot be excluded in a long-term treatment during pregnancy. During treatment in late pregnancy, there is a risk of atrophy of the cortex in the fetus, requiring in the new-born replacement therapy to stop gradually. Therefore the drug should not be administered during the first trimester of pregnancy unless clearly necessary. After the 34th week of pregnancy, Flacort should not be administered due to a possible weakness of placenta.

Particular caution is required in pregnant women with high blood pressure.

بيان التركيب:

فلازورون 6مجم، المواد الفعالة: فلازورون 6مجم.
فلازورون 30مجم، المواد الفعالة: فلازورون 30مجم.
المواد الغير فعالة: لاكتوز أحادي الهيدرات، ميكروكريستالين سيليلوز، نشأ الذرة، ستيرات الماغنيسيوم.
ما يجب معرفته عن فلاكورت: فلازورون المادة الفعالة لفلاكورت هو كورتيكوستيرويد . كورتيكوستيرويد يظل الالتهابات و كبت الحساسية و نشاط الجهاز المناعي.

وما هو استخدامهما؟

فلازورون أقراص تستخدم لعلاج العديد من الالتهابات وتشمل الربو، التهاب المفاصل، الحساسية و بعض أمراض الجلد، الكلى، القلب، الجهاز الهضمي، العين و الدم وأيضا الأورام المتحثة للأمراض. وأيضا يستخدم في عمليات زراعة الأعضاء.

من لا يتناول فلاكورت: لا تتناول فلاكورت في حالة:

- الحساسية للمعده الغير معالجة عن طريق الطبيب.
 - الحساسية للفلازورون أو أي من مكونات المنتج.
 - تلقي تطعيمات فيروسات (تحتوي علي فيروسات حيوة) يجب استشارة الطبيب.
- قبل أن تتناول فلاكورت: مثل باقي الكورتيكوستيرويد يمكن أن يخفي علامات العدوى أو أكثر عرضة للعدوى. في حالة الإصابة بعدوى تكون أنت من المرض. يجب إبلاغ الطبيب في حالة العدوى أثناء استعمال فلاكورت.
- في حالة الإصابة بالجذري أثناء استخدام الدواء (أو في خلال 3 أشهر من استخدامه) قد يكون سببا جدا. يجب تجنب الاختلاط مع المصابين بالجذري أو الهربس التنفسي. أبلغ الطبيب فوراً في حالة الاختلاط مع مرضى الجذري عن عدم إيقاف الدواء و الطبيب سوف يحدد الجرعة المناسبة و إذا كنت في حاجة إلى إضافة دواء.
- من المهم أيضاً تجنب الاختلاط بالمصابين بالحساسية وإبلاغ الطبيب فوراً في حالة وجود إصابة بالحساسية مع المخطئين بك.

يجب إبلاغ الطبيب في حالة:

- الحمل أو التخطيط للحمل.
- الرضاعة الطبيعية.
- أمراض القلب، ارتفاع ضغط الدم، الإسهال الأربعة الموية.
- مشاكل في الجهاز الهضمي وتشمل التهاب المرء، التهاب القولون التقرحي، التهاب الرئجي، قرحة هضمية.
- مرض السكر أو الإصابة بهذا المرض في العلة.
- عدوى العين بالهربس.
- هشاشة العظام.
- وهن عضلي ونبلي.
- أمراض الكلى، الكبد و الغدة الدرقية.
- أمراض نفسية أو الحالة المزاجية غير مستقرة.
- صرع.
- النزف.
- تناول كورتيكوستيرويد سابقاً و ظهور مشاكل بالعضلات.
- فلاكورت يحتوي علي لاكتوز. في حالة معرفة عدم تحمل بعض انواع السكر يجب إبلاغ الطبيب قبل تناول الدواء.
- هل يمكن تناول أدوية أخرى أثناء تناول فلاكورت:
- بعض الأدوية يمكن أن تتفاعل مع فلاكورت في حالة تناولها معا. إذا كنت قد أعطيت كارت العلاج بالسيترويد، من المهم أن يكون معك دائماً و تربية الطبيب والصيدلي أو أي أحد آخر يعطيك علاج. يجب إبلاغ الطبيب في حالة تناول أي أدوية أخرى و خصوصاً ما في الاتي:

أدوية الصرع

أدوية علاج العدوى مثل ريفاميسين و كيتوكونازول.

أمينوجليكوزيدات (لعلاج أمراض الكلى و البروستاتا).

أدوية السكر و تشمل الإنسولين.

أدوية ضغط الدم المرتفع.

مدرات البول.

مضادات التخثر.

• الأدوية التي تحتوي علي ساليسيلات مثل الأسبرين.

• الأدوية التي تحتوي علي مضادات الحموضة. لذلك يجب ترك مساعين بين تناول الدواءين.

• أقراص منع الحمل و الهرمونات.

• الأدوية الباسطة للعضلات المستخدمة مع التخدير.

كيفية تناول فلاكورت:

الطبيب يصف الجرعة المناسبة من فلاكورت. يمكن أن تكون مختلفة عن المذكورة أثناء. يمكن زيادة الجرعة أو إضافة دواء آخر في حالات العدوى، العمليات الجراحية و الأمراض الأخرى. يجب إبلاغ الطبيب بتناولك لفلاكورت في حالة كثرة علاج لأي مرض.

عادة الجرعة هي:

• البالغين: الجرعة المعتادة في أغلب الحالات بما في ذلك التهاب المفاصل الالتهابي هي من 3 إلى 18مجم يومياً عن طريق الفم، في بعض الحالات يمكن الإتيان لجرعة أولية تصل إلى 120مجم يومياً.

• فلاكورت للبالغين في الحالات الشديدة للربو يمكن أن تصل من 48 - 72مجم يومياً لمدة العلاج. وتقل الجرعة عند استقرار الحالة.

الاطفال: الجرعة حسب وزن الطفل.

• الجرعة المعتادة في التهاب المفاصل المزمن تتراوح بين 0.25 - 1.0مجم /كجم يومياً.

• الجرعة المعتادة في حالات متلازمة كلاه هي 0.5مجم/كجم/يومياً لمدة العلاج ثم تقل الجرعة تبعاً لاستجابة الطفل.

• الجرعة المعتادة في حالات الربو تتراوح بين 0.25 - 1.0مجم /كجم يومياً.

في حالة تناول جرعة أكبر من المحدد: يجب إبلاغ الطبيب فوراً.

في حالة نسيان جرعة: لا تأخذ جرعة أكبر، استمر للجرعة القادمة كالمعتاد.

في حالة إيقاف الدواء: الطبيب يحدد متى يوقف استخدام الدواء. لا توقف الدواء فجأة بدون استشارة الطبيب. المرضى الذين يستخدمون فلاكورت لفترات طويلة يمكن الشعور بعدم الراحة، سخونة أو ألم بالعضلات و المفاصل عند إيقاف الدواء. أبلغ الطبيب في حالة حدوث ذلك.

الأثار الجانبية: مثل جميع الأدوية، فلاكورت يمكن أن يكون غير ملائم لكل يمكن حدوث عدوى بصورة أسهل.

يمكن حدوث الآتي:

- مشاكل بالجهاز الهضمي: عثر هضم، قرحة، نزيف، التهاب البنكرياس، غثيان.
- إحتباس الماء و الأملاح، ارتفاع ضغط الدم، قصور القلب.
- وهن بالعضلات، هشاشة بالعظام، ضعف التئام جروح الجلد، كدمات، حب الشباب.
- سعال، دوام، دوخة، صعوبة في النوم و تملأ، مشاكل مزاجية، إكتئاب، زيادة الإثارة، تقادم السرعة و النقص.
- حساسية (طفح جلدي، حكة وأحياناً صعوبة التنفس).
- اضطرابات هرمونية (خصوصاً الغدة الكظرية) وتتمثل زيادة نمو الشعر، زيادة الوزن، زيادة الشهية، الداء السكري واضطرابات الدورة الشهرية.
- الإستخدام لفترات طويلة يمكن أن يؤدي إلى كثرة/تآمة/عمسة العين، زيادة ضغط العين في بعض المرضى.
- وأيضا يمكن أن يخفي عدوى العين. الإستعمال لفترات طويلة للأطفال يمكن أن يوقف أو يوخر النمو.
- الأثار الجانبية يمكن أن تصبح أشد خطورة في كبار السن و الطبيب يتابع المرضى بصورة منتظمة.
- في حالة ظهور أي آثار غير معتادة يجب إبلاغ الطبيب فوراً.

المخاطر وظروف التخزين: يحفظ بعيداً عن متناول الأطفال، يحفظ في درجة حرارة لا تتعدى 30 درجة مئوية في مكان جاف.

فلاكورت 6مجم: عبوة كرتون بها شريط أو شريطين (الواي في سي) بكل منهما 10 أقراص ونشرة مرقة.

فلاكورت 30مجم: عبوة كرتون بها شريط أو شريطين (الواي في سي) بكل منهما 10 أقراص ونشرة مرقة.

إنتاج:

المجموعة المصرية للصناعات الدوائية

It should be explained to the patient that she should immediately notify her doctor if she suspects or if she finds she is pregnant.

Newborns whose mothers received high doses of glucocorticosteroids during pregnancy should be carefully monitored for any signs of hypocorticism and the need for substitution treatment is stopping gradually.

Breastfeeding: Glucocorticoids are excreted in breast milk and may affect the growth of infants and reduce the production of endogenous steroids. Therefore, breastfeeding is proscribed during treatment with glucocorticoids.

Effect on ability to drive and use machines: No studies evaluating the influence on ability to drive or use machines available. On the basis of side effects (dizziness, convulsions), influence is not excluded.

Adverse Effects: The frequency and severity of side effects vary depending on dosage, duration of treatment, as well as age, sex and causative disease patient.

The short-term administration of glucocorticoids, even at high doses, do not produce side effects. We will monitor the intestinal ulcerations, however (often due to stress), whose symptoms may be obscured during a corticosteroid.

By contraindication a long-term treatment with high doses can cause the same side effects as all other corticosteroids.

Infections: Increased risk of infections.

Blood/Stream: Leukocytosis, eosinopenia.

Immune System: Decreased response to vaccines and skin tests; immunosuppression, in rare cases, allergic reactions.

Endocrine: Weight gain with cushingoid distribution and moon face, hirsutism, amenorrhea, decreased glucose tolerance (especially diabetes), diabetes mellitus, inhibition of ACTH secretion, suppression of the hypothalamic-pituitary axis; disorders growth in children.

Sodium and water retention, depletion of potassium, calcium and phosphate, hypokalemia, alkalosis, ketoacidosis.

Nervous System: Headache, dizziness, euphoria, insomnia, anxiety, convulsions, depression, pseudotumor cerebri (in children).

Eye disorders: Cataract, posterior subcapsular, especially in children, ocular hypertension, decreased resistance to eye infections caused by fungi or viruses.

Cardiovascular Disorders: Increased risk of thrombosis and in isolated cases of myocardial rupture after acute myocardial infarction, hypertension, congestive heart failure.

Gastro-intestinal: Dyspepsia, peptic ulcer, perforation of a peptic ulcer, bleeding, acute pancreatitis, especially in children.

Skin disorders: Delayed healing, atrophy, striae, erythema, petechiae, bruises, acne, increased sweating.

Musculoskeletal: Myopathy with muscle weakness (especially in cases of concomitant non-depolarizing muscle relaxants); osteoporosis aseptic necrosis of femoral or humeral head.

Overdose: Acute corticosteroids is low. Possible symptoms of poisoning are a sodium and water retention with edema and hypertension, hypokalemia alkalosis, diabetes induced by steroids, excitation and insomnia.

There is no specific antidote for overdose, treatment is symptomatic.

In case of overdose Chronic, is expected to increase the number of side effects and risks described under "warnings and precautions."

Properties / Effects:

• Deflazacort is a synthetic glucocorticoid, which differs from prednisolone by an oxazoline nucleus, C16-C17.

• Deflazacort has, like other glucocorticoids, an anti-inflammatory and immunosuppressive. The mineralocorticoid effects of deflazacort is very low.

• The effect of deflazacort is, as with all glucocorticoids on the stimulation or inhibition of intracellular synthesis of specific proteins. They are responsible for specific biological effects. As the mechanism of action involves the cell nucleus, all of the pharmacological effect of glucocorticoids appears late (several hours after oral administration or parenteral), and extends more than suggested by the plasma half-life of principle action. The duration of anti-inflammatory effect of a single dose of deflazacort is approximately equivalent to the duration of the suppression of the hypothalamic-pituitary-adrenal.

• The anti-inflammatory dose of 7.5 mg of deflazacort is equivalent to approximately 0.7 mg dexamethasone, 5 mg of prednisone or prednisolone, 20 mg hydrocortisone or 25 mg of cortisone.

Pharmacokinetics:

Absorption: After oral administration, deflazacort (D) is almost completely absorbed and immediately metabolized into 21-hydroxydeflazacort (D-OH-21), pharmacologically active.

Distribution: The distribution volume of D-21-OH reached 1.48 l / kg.

The D-21-OH is a highly soluble glucocorticoid. In humans, 40% of D-21-OH are bound to plasma proteins, unlike prednisone, he has no affinity for the corticosteroid binding globulin (transcortin).

The maximum plasma concentration (Cmax) D-21-OH is reached after 1.5 to 2 hours, but the maximum pharmacological effect occurs only several hours after administration. Only very small amounts of deflazacort cross the blood-brain barrier.

Metabolism: The D-OH-21 is extensively metabolized, mainly in the liver. The main metabolite is a derivative of 6-hydroxy-beta.

Elimination: The half-life of plasma D-OH-21 varies between 1.1 and 1.9 h. Elimination is primarily by renal excretion. Within the first 8 hours after administration, 70% of the administered dose is excreted in the urine, the remaining 30% in feces. Only 18% is excreted unchanged in urine. The fraction of the main metabolite in urine, a derivative of 6-beta-hydroxy, amounts to about 33%.

Kinetics in clinical situations: There are no data on the use of deflazacort in clinical situations where the kinetics may be altered. It is known for other glucocorticoids in cases of severe liver disease and hypothyroidism, the metabolism may be slowing, which may enhance the action of glucocorticoid. On the other hand, excessively high concentrations of active unbound protein (that is to say, pharmacologically active) may occur if

hypalbuminemia and hyperbilirubinemia.

The half-life is prolonged glucocorticoid during pregnancy and the plasma clearance is lower in neonates than in children and adults.

Preclinical data: In animal studies, it has been demonstrated teratogenic dose-dependent for deflazacort. No other study is available.

Special Notes, Influence on diagnostic: Corticosteroids may affect the test nitroblue tetrazolium designed to investigate the presence of bacterial infections and give false negatives.

storage: Store at a temperature not exceeding 30 °C in a dry place.

Keep out of reach of children.

Package:

Factort 6 mg: Carton Box containing 1 or 2 strips (AL/PVC) each one contains 10 tablets with inner leaflet.

Factort 30 mg: Carton Box containing 1 or 2 strips (AL/PVC) each one contains 10 tablets with inner leaflet.

Manufactured by:

Egyptian Group for Pharmaceutical Industries.

