PACKAGE LEAFLET: Information for the patient

CUTASON

Tablets – 20 mg

(Prednisone)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on others. It may harm them, even if their signs of illnes are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT CUTASON IS AND WHAT IT IS USED FOR

Cutason contains the active substance prednisone which is a glucocorticoid (adrenal gland hormone) that influences in the metabolism, in the salts balance (electrolites) and tissue functions.

Cutason is used for the treatment of diseases that need systemic treatment with glucocorticoids.

Depending on the appearance and severity these include:

(DS dosing regimens: a to d and dosage e, see section 3).

Hormone replacement therapy:

- adrenal insufficiency of any cause (e.g. Addison disease, adrenogenital syndrome, adrenalectomy, ACTH deficiency) beyond the growth age (the first choice is hydrocortisone and cortisone);
- stress disorder after long-term corticosteroid therapy.

Rheumatic disorders

- Active phases of vascular inflammation:
  - polyarteritis nodosa (Dosage: a, b, with positive serology for hepatitis B, treatment time limited to two weeks);
  - giant cell arteritis, pain and stiffness of the muscles (polymyalgia rheumatica) (Dosage: c);
  - temporal arteritis (Dosage: a, by acute visual loss, initial high intravenous loading dose with glucocorticoids and long-term therapy with control of erythrocyte sedimentation);
  - Wegener's granulomatosis: induction therapy (Dosage: a-b) in combination with methotrexate (mild forms without renal involvement) or according to the Fauci scheme (severe forms with kidney and / or pulmonary involvement), remission maintenance: (Dosage: d, creeping) in combination with immuno suppressants;
  - Churg-Strauss syndrome: initial therapy (Dosage: a-b), in organ manifestations and severe courses in combination with immunosuppressants, remission maintenance (Dosage: d).
- During active phases of systemic rheumatic diseases (Dosage: a, b):
  - systemic lupus erythematosus that affects internal organs, polymyositis / polychondritis chronica atrophicans, mixed collagenosis.
- Active rheumatoid arthritis with severe progressive course forms (Dosage: a to d), such as fast running destructive reversible forms (Dosage a) and / or non-articular manifestations (Dosage: b).
- Other inflammatory rheumatic arthritis, if the severity of the disease requires it and non-steroidal antirheumatics (NSAIDs) had no effect or cannot be used:
  - spondylarthritides (ankylosing spondylitis) with peripheral joint involvement (Dosage: b, c), psoriatic arthritis (Dosage: c, d);
  - enteropathic arthropathy with high inflammatory activity (Dosage: a);
  - reactive arthritis (Dosage: c);

- arthritis in sarcoidosis (Dosage: b initial);
- severe arthritis that occurs without obvious cause in adolescents (juvenile idiopathic arthritis with severe systemic form (Still's disease), or iridocyclitis not being influenced by local treatment (Dosage: a);
- carditis in rheumatic fever, in severe cases over 2-3 months (Dosage: a).

Bronchial and lung diseases

- bronchial asthma (Dosage: c-a), at the same time, the administration of bronchodilators is recommended;
- acute exacerbation of COPD (Dosage: b), recommended treatment duration up to 10 days;
- interstitial lung diseases such as acute alveolitis (Dosage: b), pulmonary fibrosis (Dosage: b), bronchiolitis obliterans organizing pneumonia (BOOP) (Dosage: b decreasing gradually), possibly in combination with immunosuppressants, chronic eosinophilic pneumonia (Dosage: b decreasing gradually) for long-term treatment of chronic forms of sarcoidosis in stages II and III (with dyspnea, cough and deterioration in pulmonary function values) (Dosage: b);
- prevention of respiratory distress syndrome in preterm infants (Dosage: b, twice).

Diseases of the upper respiratory tract:

- severe forms of pollinosis and allergic rhinitis, after failure of intranasally administered glucocorticoids (Dosage: c);
- acute laryngeal and tracheal stenoses: angioedema, obstructive laryngitis subglottica (pseudo-croup) (Dosage: b to a).

Skin diseases:

- Diseases of the skin and mucous membranes, which due to their severity and / or expansion or system involvement cannot be treated adequately with topical glucocorticoids; these include:
  - allergic, pseudo-allergic and infectious allergic diseases: such as acute urticaria, anaphylactoid reactions;
  - severe skin diseases such as: drug eruption, erythema multiforme, toxic epidermal necrolysis (Lyell's syndrome), pustulosis acuta generalisata, erythema nodosum, acute

febrile neutrophilic dermatosis (Sweet's syndrome), allergic contact dermatitis (Dosage: b to a);
  - eczema disorders: e.g., atopic dermatitis, contact dermatitis, microbial (nummular) eczema (Dosage: b to a);
  - severe skin diseases such as granulomatous diseases: e.g. sarcoidosis, granulomatous cheilitis (mono symptomatic Melkersson-Rosenthal syndrome) (Dosage: b to a);
- Severe skin diseases that appear with blistering on the skin: such as pemphigus vulgaris, bullous pemphigoid, benign mucous membrane pemphigoid, linear IgA dermatosis (Dosage: b to a);
- Vasculitis: e.g.: allergic vasculitis, polyarteritis nodosa (Dosage: b to a);
- Autoimmune diseases: e.g.: dermatomyositis, systemic sclerodermia (indurative phase), chronic discoid and subacute cutaneous lupus erythematosus (Dosage: b to a);
- Pregnancy dermatoses (see also Section “Pregnancy and breast-feeding”): e.g., Herpes gestationis, impetigo herpetiformis (Dosage: d to a);
- Erythemato-squamous dermatoses: e.g. pustular psoriasis, pityriasis rubra pilaris, parapsoriasis group (Dosage: c to a);
- Erythroderma, even with Sezary Syndrome (Dosage: c to a);
- Other diseases: e.g. Jarisch-Herxheimer reaction in penicillin treatment of syphilis, quickly and supplanting growing cavernous hemangioma, Behçet's disease, pyoderma gangraenosum, eosinophilic fasciitis, lichen planus exanthematicus, epidermolysis bullosa hereditaria (Dosage: c to a).

<u>Hematology / Oncology:</u>

- Autoimmune blood disorders:
  - anemia caused by red blood cells destruction (autoimmune hemolytic anemia) (Dosage: c to a);
  - idiopathic thrombocytopenic purpura (Werlhof's disease) (Dosage: a);
  - acute intermittent thrombocytopenia (Dosage: a);
- Malignant diseases such as:
  - acute lymphoblastic leukemia (Dosage: e):
  - Hodgkin's disease (Dosage: e);

  - non-Hodgkin's lymphoma (Dosage: e);
  - chronic lymphocytic leukemia (Dosage: e);
  - Waldenstrom's macroglobulinemia (Dosage: e);
  - multiple myeloma (Dosage: e);
  - hypercalcemia in malignant diseases (Dosage: c to a);
- Prophylaxis and treatment of cytotoxic-induced emesis (Dosage: b to a);
- Palliative therapy in malignant diseases.

Note: Cutason 20 mg can be used to relieve symptoms, such as loss of appetite, weight loss and general weakness in advanced malignant diseases after other specific treatment options have been used without success.

Nervous system disorders

- myasthenia gravis (first choice medicine is azathioprine);
- chronic Guillain-Barré syndrome;
- Tolosa-Hunt syndrome;
- polyneuropathy in monoclonal gammopathy;
- multiple sclerosis (for oral tapering after high-dose parenteral glucocorticoid use in an acute attack);
- some epilepsy forms in infants (BNS-cramps).

Specific progressive forms of infectious diseases:

- toxic states under severe infectious diseases (in combination with antibiotics / chemotherapy), such as tuberculous meningitis (Dosage: b), severe form of pulmonary tuberculosis (Dosage: b).

Eye diseases (Dosage: b to a):

- for systemic diseases with ocular involvement and in immunological processes in the orbit and in the eye: optic neuropathy (e.g., giant cell arteritis, anterior ischemic optic neuropathy (AION), traumatic optic neuropathy, Behçet’s disease, sarcoidosis, endocrine orbitopathy,

pseudotumor of the orbit, transplant rejection and certain uveitis as Harada disease and sympathetic ophthalmia.

In the following illnesses, Cutason 20 mg is indicated only after unsuccesful local treatment:

- inflammation of different parts of the eye: scleritis, episcleritis, keratitis, chronic cyclitis, uveitis, allergic conjunctivitis, alkali burns, in conjunction with antimicrobial therapy for autoimmune or syphilis-associated interstitial keratitis, in stromal herpes simplex keratitis only by intact corneal epithelium and under regular ophthalmological control.

Gastrointenstinal disorders / liver diseases:

- Colitis ulcerosa (Dosage: b to c);
- Morbus Crohn (Dosage: b);
- autoimmune hepatitis (Dosage: b);
- corrosion of the oesophagus (Dosage: a).

Kidney diseases:

- autoimmune kidney diseases: Nil disease (minimal change glomerulonephritis) (Dosage: a), extracapillary proliferative glomerulonephritis (rapid progressive glomerulonephritis) (Dosage: loading doses, usually in combination with cytostatics), in reduction and termination of treatment in Goodpasture syndrome, long-term continuation of treatment in all other forms (Dosage: d).

2. BEFORE YOU TAKE CUTASON

Do not take Cutason if:

- you are hypersensitive (allergic) to prednisone or any of the excipients of Cutason 20 mg.

There are no other contraindications during short-term use of Cutason 20 mg in vital indications (except hypersensitivity reactions that are mentioned above).

Take special care with Cutason

If you need higher doses than those used in hormone replacement therapy.

In the following diseases, Cutason 20 mg should be used only if your doctor sees it necessary.

Treatment with Cutason tablets may increase the risk of bacterial, viral, parasitic, opportunistic and fungal infections through immunosuppression. The symptoms of an existing or developing infection can be masked and thus the diagnosis may become difficult. Latent infections such as tuberculosis or hepatitis B can be reactivated.

If necessary, you should receive concomitantly, an additional targeted anti-infective therapy in the following diseases:

- acute viral infections (hepatitis B, herpes zoster, herpes simplex, varicella, herpetic keratitis);
- acute and chronic bacterial infections;
- systemic fungal and parasitic infections (such as amoeba, nematodes);
- in patients with suspected or confirmed strongyloidiasis, Cutason 20 mg may lead to the activation and mass propagation of the parasites;
- lymphadenitis after BCG vaccination (in history of tuberculosis reactivation cave can be used only with antitubercular protection);
- HBsAg positive chronic active hepatitis;
- poliomyelitis;
- 8 weeks before and 2 weeks after immunization with live vaccines.

Additionally, Cutason 20 mg can be used in the following diseases only if your doctor sees it necessary and if these diseases are treated concomitantly with the additional specific therapy:

- gastrointestinal ulcers;
- uncontrolled hypertension;
- sever diabetes mellitus;
- osteoporosis;
- psychiatric disorders (including medical history), including suicidality: neurological or psychiatric surveillance is recommended;
- narrow and wide angle glaucoma; ophthalmological monitoring and concomitant therapy is recommended;
- corneal ulcerations and corneal damage; ophthalmological monitoring and concomitant therapy is recommended.

Because of the risk of intestinal perforation (which can lead to peritonitis), Cutason 20 mg could be used only if clearly necessary and under proper supervision at:

- severe ulcerative colitis with impending perforation, abscess or maturation;
- diverticulitis (inflammatory pouches on the intestinal wall);
- enteroanastomosis (immediately after surgery).

Signs of peritoneal irritation following gastrointestinal perforation may be absent in patients receiving high doses of glucocorticoids.

The risk of tendon discomfort, tendinitis, and tendon rupture is increased when fluoroquinolones and Cutason are co-administered.

At the beginning of the treatment of myasthenia gravis with Cutason 20 mg, a symptom deterioration may occur initially. In this case the adjustment of corticosteroids dose should be performed in hospital. Especially in severe facio-pharyngeal symptoms and reduced tidal volume, therapy with Cutason 20 mg should be started very cautiously.
Treatment with Cutason 20 mg may mask the symptoms of an existing or developing infection, making it difficult to diagnose.

A long-lasting use, even of small amounts of prednisone, leads to an increased risk of infections by such microorganisms, which otherwise rarely cause infections (so-called opportunistic infections).
Vaccinations with dead vaccines are generally possible. It should be noted, however, that the immune response, and thus the response to the vaccine may be compromised at higher doses of Cutason 20 mg.

In a prolonged therapy with Cutason 20 mg, regular medical controls (including ophthalmological controls every three months) are made.

In diabetic patients, a possible elevated need for insulin or oral hypoglycemic agents must be taken into account. These patients should undergo in regular medical examinations to keep the metabolism under control.

During long-term treatment with relatively high doses of Cutason 20 mg care should be taken to obtain sufficient potassium (e.g. from vegetables, bananas, etc.) and to limit the amount of salt. Potassium levels in the body should be kept under the control of the doctor.

Serious anaphylactic reactions may occur.

If you suffer from hypertension or, cardiac insufficiency, a regular monitoring of blood pressure is required, as a deterioration of the situation may occur.

If during treatment with Cutason 20 mg you are undergoing a fever-related illness, accident or surgery, you should immediately inform the doctor or outpatient center for the treatment. It may be necessary to temporarily increase the daily dose of Cutason 20 mg.

If treatment with Cutason 20 mg lasts for a long period of time, the doctor should provide you with a specific card, which you should always carry with you.

Depending on the dosage and duration of treatment, a negative effect on calcium metabolism is to be expected, so that osteoporosis prophylaxis is recommended. This applies especially when there are existing risk factors such as familial predisposition, advanced age, insufficient protein and calcium intake, heavy smoking, excessive alcohol consumption, after menopause period and lack of physical activity. Prevention consists in adequate calcium and vitamin D intake, and physical activity. In existing osteoporosis, additional drug therapy should also be considered.

Upon termination or possible interruption of long-term administration, the following risks should be borne in mind: exacerbation or relapse of the underlying disease, acute adrenal insufficiency (especially in stressful situations, e.g. during infections, after accidents, in increased physical stress), cortisone withdrawal syndrome.

In patients treated with Cutason 20 mg, specific viral diseases (chicken pox, measles) may run particularly hard. Particularly vulnerable are immunocompromised (immunosuppressed) children and persons without previous chickenpox or measles infection. When these individuals during treatment with Cutason 20 mg have contact with measles or chickenpox affected persons, should contact immediately the doctor. In these cases, a preventive treatment should be initiated.

Contact your doctor if you experience blurred vison or other visual disturbances.

Talk to your doctor before taking Cutason 20 mg if you have scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15 mg or more may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production. The doctor may advise that you have your blood pressure and urine regularly checked.

Children and adolescents
Since treatment with Cutason 20 mg may inhibit growth in children, this medicine should be used only if the doctor sees it necessary and the child's growth should be monitored continuously. Therapy with Cutason 20 mg should be limited in time or alternating during long-term therapy (e.g., every other day [alternating therapy]).

Elderly patients
Since elderly patients have an increased risk of osteoporosis, the benefit-risk balance of treatment with Cutason 20 mg should be carefully considered.

Effects of misuse for doping purposes
The use of Cutason 20 mg can lead to positive results during doping controls. The health consequences of using Cutason as doping agent can not be foreseen, serious health risks can not be excluded.

Taking other medicines

Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

Some medicines may increase the effects of Cutason and your doctor may monitor you carefully if you are taking them (including some medicines for HIV treatment: ritonavir, cobicistat):

- medicines that induce liver metabolism (barbiturates, phenytoin, carbamazepine, primidone [for the treatment of convulsions], rifampicin [for the treatment of tuberculosis]): the effect of Cutason can be reduced;
- ephedrine (can be found in drugs for hypotension, chronic bronchitis, asthma attacks and swollen nasal mucous membranes and as constituents of appetite suppressants): the accelerated degradation can reduce the efficacy of Cutason;
- drugs that slow down liver metabolism, such as some antimycotics (ketoconazole, itraconazole) may increase the effect of Cutason;
- some female sexual hormones (estrogens), such as contraceptives: the half-life of glucocorticoids may be prolonged;
- medicines that act against excessive acid production in the stomach (antiacids): coadministration of magnesium or aluminium hydroxide may reduce prednisone absorption; therefore, these two medicines should be taken at intervals of 2 hours from each other.

Taking Cutason at the same time with:

- medicines that act in cardiac tonus (cardiac glycosides): the effect of glycosides can be enhanced by potassium deficiency;
- diuretics / laxatives: potassium excretion is increased;
- diabetes medications (antidiabetics / insulin): the hypoglycemic effect is reduced;
- anticoagulants (oral anticoagulants / coumarin derivatives): the anticoagulant effect is reduced or enhanced;
- non - steroidal antiphlogistic / antirheumatic agents, salicylates and indomethacin:
- the risk of peptic ulcer and gastrointestinal bleeding is increased;
- muscle relaxant medicines (non-depolarizing muscle relaxants): muscle relaxation may last longer;

- ophthalmologic medicines (atropine), other anticholinergics: additional increase of intraocular pressure is possible during concomitant use with Cutason;
- medicines for the treatment of diseases caused by worms (praziquantel): orticosteroids may decrease the blood concentration of praziquantel;
- medicines for the treatment of malaria and rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine): there is an increased risk of developing myopathy, cardiomyopathy;
- growth hormone (somatropin): the effects of somatropin may decrease, especially from the use of high doses of Cutason 20 mg;
- protirelin (mid - brain hormone): the TSH increase after taking protirelin may be reduced;
- immunosuppressant substances: coadministration of these medicines with Cutason 20 mg can increase susceptibility to infections and can exacerbate latent infections;
- cyclosporine (used to suppress the immune system of the organism) the blood levels of cyclosporine may be increased: there is an increased risk of cerebral seizures;
- certain medicines that are used to treat high blood pressure (ACE inhibitors): increased risk of occurrence of blood dyscrasias;
- fluoroquinolones (antibiotics), can increase the risk of tendon rupture.

Impact on laboratory analysis

Skin reaction in allergy tests may be prevented.

Pregnancy and lactation

Ask your doctor before taking / using any medicine.

Pregnancy

During pregnancy, this medicine should be given only by prescription. Inform your doctor if you are pregnant.

During long-term treatment with Cutason 20 mg in pregnancy, growth retardation of the fetus cannot be excluded. If Cutason 20 mg is given at the end of pregnancy, there is a risk of atrophy of the adrenal cortex of the fetus which may require replacement therapy. Studies in animals

have shown side effects in newborns (e.g. cleft palate). There is an increased risk of oral clefts in human fetuses by administration of prednisone during the first trimester of pregnancy.

Breastfeeding

Prednisone passes in small amounts in breast milk. A harm to the infant is not known so far. Nevertheless, the indication during lactation should be assessed under severe evaluation. If higher doses of Cutason 20 mg are needed, you should not breastfeed your child. Call your doctor immediately.

Effects on ability to drive and use machines

So far there is no evidence that Cutason 20 mg affects the ability to drive, or to operate machinery. The same applies to work without a secure hold.

Important information about some of the excipients of Cutason

This medicine contains lactose. If you have an intolerance to some sugars, ask your doctor before taking Cutason 20 mg.

3. HOW TO TAKE CUTASON

Always take Cutason 20 mg as your doctor has told you. The individual dose is determined by your doctor.

Please see the leaflet, otherwise Cutason 20 mg may not act properly. If you are not sure, contact your doctor or pharmacist.

Method of administration

The tablets should be swallowed whole with some liquid before or after the meals. Hormone replacement therapy in chronic insufficiency of the adrenal glands is life-long. Depending on the disease to be treated and the individual response, your doctor will evaluate the possibility of alternate treatment (on alternate days).

If not otherwise prescribed by your doctor, the usual doses are:

Hormone replacement therapy (beyond the growth age):

5 to 7.5 mg prednisone / day in two divided doses (morning and noon, in adrenogenital syndrome in the morning and evening), if necessary, a mineralcorticoid (fludrocortisone) may be used in addition. In particular physical stress e.g., trauma, surgery, intercurrent infections or labour, the dose should be increased temporarily, as your doctor advices you.

Stress disorder after long-term glucocorticoid treatment: at first up to 50 mg of prednisone / day. Dose reduction is realized through several days.

Treatment of certain diseases (pharmacoterapy)

The tables below summarize the general dosage guidelines:

1. Adults (Dosage scheme a – d)

Dosage	Dose in mg / day	Dose in mg / kg BW / day
a) High	80 - 100 (250)	1,0 - 3,0
b) Average	40 - 80	0,5 - 1,0
c) Low	10 - 40	0,25 - 0,5
d) Very low	1,5 - 7,5 (10)	./.

Dosage e) for blood disorders through specific treatment schemes, see below:

In general, the total daily dose is taken between 6.00 and 8.00 in the morning. High daily doses, depending on the disease, can also be divided to 2-4 average daily doses, taken 2-3 times.

2. Children

Posology	**Dose in mg / kg BW / day**
High doses	2 - 3
Average doses	1 - 2
Maintenance dose	0,25

Children should take the minimal possible dose.

In special cases (e.g. BNS cramps) deviations from this recommendation are accepted.

Reduction of doses

After achieving the desired effect, and depending on the underlying disease, the reduction of the dose is started. After distribution of the daily dose to multiple doses, the evening dose should be reduced first and then any midday dose. After that, the dose will be reduced in somewhat larger steps, below a dose of approximately 30 mg / day the reduction should be in smaller steps. The clinical situation determines the duration of treatment. After achieving the desired effect, the dose may be reduced to a maintenance dose or the treatment is stopped. Your doctor will prescribe the dosage schedule, which you have to follow strictly.

While observing the disease activity, the following steps may serve as orientation for dose reduction:

over 30 mg / day	reduction by 10 mg	every 2 - 5 days
30 to 15 mg / day	reduction by 5 mg	every week
15 to 10 mg / day	reduction by 2.5 mg	every 1 - 2 weeks
10 to 6 mg / day	reduction by 1 mg	every 2 - 4 weeks
under 6 mg / day	reduction by 0.5 mg	every 4 - 8 weeks

High and very high doses, which are given over a few days, can be reduced without tapering off depending on the underlying disease and clinical response.

In hypothyroidism or liver cirrhosis relatively low doses may be sufficient, or a dose reduction may be necessary.

Talk to your doctor or pharmacist if you feel that the effect of Cutason 20 mg is too strong or too weak.

<u>Dosage e)</u>

This generally is applicable when using single-dose prednisone without tapering required in the end of therapy. Referring to the literature, the respective prednisone posologies in established chemotherapy protocols are mentioned here as follows:

- non-Hodgkin-lymphoma: CHOP-regimen, prednisone 100 mg / m² day 1-5;
- COP-regimen, prednisone 100 mg/m² day 1-5;
- chronic lymphocytic leukemia: Knospe regimen, prednisone 75 / 50 / 25 mg day 1-3;
- Hodgkin’s disease: COPP-ABVD-regimen, prednisone 40 mg / m² day 1-14;

- multiple myeloma: Alexanian-regimen, prednisone 2 mg /kg BW day 1-4.

If you take more Cutason than you should

Generally, Cutason 20 mg is well tolerated, without complications even when high doses are taken for a short period of time. No special measures are necessary. If you notice any side effects or unusual side effects, consult with your doctor.

If you forget to take Cutason

Do not take a double dose to make up the forgotten dose.

You can compensate the missed dose during the day and in the next few days as your doctor has prescribed.

If you forget to take a dose several times, there may be a recurrence or deterioration of the illness that you are being treated for. In these cases, consult with your doctor who will assess the situation and decide if a dosage adjustment is needed.

If you stop taking Cutason

Always follow the dosage schedule that your doctor has prescribed to you. Cutason 20 mg should never be given without a doctor's prescription, especially because long-term treatment with Cutason 20 mg can lead to the reduction of glucocorticoid production from the body.

A severe physical state of stress can be life-threatening (the Addisonian crisis).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cutason 20 mg can cause side effects, although not everybody gets them.

Hormone Replacement Therapy: low risk of side effects if the recommended doses are used.

Treatment of certain diseases, using higher doses than those used in hormone replacement therapy

Depending on the dose and duration of therapy, the following side effects may occur:

Infections and infestations

Masking of infection, manifestation, exacerbation or reactivation of viral infections, fungal infections, bacterial, parasitic and opportunistic infections, activation of infestations.

Blood and lymphatic system disorders

Blood disorders (moderate leukocytosis, lymphopenia, eosinopenia, polycythemia).

Immune system disorders

Allergic reactions (e.g. drug eruption), severe anaphylactic reactions such as arrhythmias, bronchospasm, hypo- or hypertension, circulatory collapse, cardiac arrest, weakening of the immune system.

Endocrine disorders

Adrenal suppression and induction of Cushing syndrome (typical symptoms: moon face, central obesity, hot flushes), insufficiency or atrophy of the adrenal cortex.

Metabolism and nutrition disorders

Weight gain, impaired glucose tolerance, diabetes mellitus, hypercholesterolemia and hypertriglyceridemia, edema, potassium deficiency as a result of increased potassium excretion (caution: arrhythmias), increased appetite.

Psychiatric disorders

Depression, irritability, euphoria, psychosis, mania, hallucinations, mood disorders, anxiety, sleep disorders, suicidality.

Nervous system disorders

Pseudotumor cerebri, manifestation of latent epilepsy and increased seizure readiness in manifested epilepsy.

Eye disorders

Intraocular pressure increase (glaucoma), cataracts, worsening symptoms of corneal ulcer, favoring of viral, fungal and bacterial infections of the eye, blurred vision, an increased risk of central serous chorioretinopathy. You should consult with an oculist regularly.

Vascular disorders

Hypertension, increase of the risk of atherosclerosis and thrombosis, vasculitis (also known as withdrawal syndrome after long-term treatment), increase of vascular fragility.

Gastrointestinal disorders

Gastrointestinal ulcers, gastrointestinal bleeding, pancreatitis.

Skin and subcutaneous tissue disorders

Striae rubrae, atrophy, telangiectasias, increased capillary fragility, petechiae, ecchymoses, hypertrichosis, steroid acne, delayed wound healing, rosacea-like (perioral, near the nose and eyes) dermatitis, changes in skin pigmentation, hypersensitivity reactions, such as drug eruption.

Musculoskeletal and connective tissue disorders

Muscle atrophy and weakness, osteoporosis (dose related, possible even with only short-term use), aseptic bone necrosis (such as that of the head of the humerus and the femur), tendinitis, tendon ruptures and epidural lipomatosis, growth inhibition in children.
Note: If after long-term treatment, the dose reduction is too rapid, this can lead to symptoms such as muscle and joint pain.

Reproductive system and breast disorders

Disorders of sexual hormone secretion (as a result of which amenorrhea, hirsutism, impotence may occur).

General disorders and administration site conditions

Delayed wound healing.

Side effects where the frequency is unknown

Renal and urinary disorders

Scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.

Cardiac disorders

Slow heart rate.

Reporting of side effects

Please tell your doctor or pharmacist if you experience these side effects or if you notice any other side effect not listed in this leaflet during treatment with Cutason 20 mg.
Do not stop treatment without consulting your doctor.
If you have gastrointestinal disturbances, pain in the midline, shoulder or abdomen, mental problems, high blood sugar levels (diabetics) or other concerns, tell your doctor immediately.
Please tell your doctor or pharmacist if any of these side effects gets serious or if you notice any other side effects not listed in this leaflet.

5. HOW TO STORE CUTASON

Keep out of the reach and sight of children.
Do not use after the expiry date which is stated on the blister and carton box.
Store below 25°C.

6. OTHER INFORMATION

What Cutason 20 mg contains

The active substance is Prednisone, an adrenal gland hormone.
One tablet contains 20 mg prednisone.
The excipients are: pregelatinized starch, lactose monohydrate, sodium starch glycolate (Type A), colloidal anhydrous silica, magnesium stearate, purified talc, sicovit yellow E172.

Pack content

Carton box with 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

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