

PACKAGE LEAFLET: Information for the user

CUTASON

Tablets – 5 mg

(Prednisone)

Read all of 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. Do not pass it on to others. It may harm them, even if their symptoms 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?
2. Before you take Cutason
3. How to take Cutason?
4. Possible side effects
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6. Further information

1. WHAT CUTASON IS AND WHAT IT IS USED FOR?

Cutason is a glucocorticoid (adrenal hormone) with effects on metabolism, on salt (electrolyte)-balance and on tissue function.

Cutason is used for diseases that need systemic treatment with glucocorticoids. Depending on the appearance and severity these include:

(Posology table with doses: **DS: a to d** and **e dosage**, see Section 3: Posology):

Hormone replacement therapy in:

- reduced or absent adrenal function (adrenal failure) from any cause (e.g., Addison's disease, adrenogenital syndrome, surgical removal of the adrenal gland, underactive pituitary gland) beyond the growth ages (the first choice is hydrocortisone and cortisone)
- stress conditions after long-term treatment with corticoids.

Rheumatic diseases:

- active phases of vascular inflammation (DS: a, b):
 - nodular inflammation of the vessel walls (polyarteritis nodosa) (at existing hepatitis B infection, treatment time limited to two weeks)
 - giant cell arteritis, muscle pain and stiffness (polymyalgia rheumatica) (DS: c)
 - inflammation especially of the temporal artery (arteritis) (DS: a), in acute loss of vision initially loading doses with glucocorticoids in the vein and chronic treatment with control of the 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 immunosuppressants
 - Churg-Strauss syndrome: initial therapy (Dosage: a-b), in organ manifestations and severe courses in combination with immunosuppressants, remission maintenance (Dosage: d)
- active phases of rheumatic diseases that can affect internal organs (DS: a, b): internal organs with lupus erythematosus, muscle weakness and pain (polymyositis), inflammation of the cartilage (polychondritis chronica atrophicans), connective tissue disease (MCTD)
- progressive rheumatoid arthritis (DS: a to d) with severe progressive course form, e.g. rapidly destroying remitting forms (DS: a) or the forms that do not concern the joints (DS: b)
- other inflammatory rheumatic diseases of the joints, if the severity of the disease requires it and certain medicines for rheumatic diseases (NSAIDs) are not effective or can not be used
- inflammatory changes, especially in the spine (spondylarthritides), inflammation of the spine and alteration (ankylosing spondylitis) with involvement of other joints such as the arms and legs (DS: b, c), joint involvement in psoriasis (psoriatic arthritis) (DS: c, d), joint disease caused by gastrointestinal diseases (enteropathic arthropathy) with high inflammatory activity (DS: a)
- arthritis in response to other underlying diseases (DS: c)
- joint inflammation in sarcoidosis (DS: b at the beginning)
- arthritis arising without apparent cause in adolescents (juvenile idiopathic arthritis) with severe running form concerning internal organs (Still's disease), or ocular involvement

not being influenced by local treatment (inflammation of the iris and the adjacent parts)
(DS: a)

- heart inflammation in rheumatic fever, in severe cases over 2-3 months (DS: a).

Bronchial and lung diseases:

- asthma (DS: c-a), at the same time, we recommend the use of medicines for bronchodilation
- acute exacerbation of existing chronic, constricting airways disease (DS: b), recommended treatment time: up to 10 days
- specific lung diseases such as acute inflammation of the alveoli (alveolitis) (DS: b), hardening of the lung tissue and lung remodeling (pulmonary fibrosis) (DS: b), bronchiolitis obliterans organizing pneumonia (BOOP) (Dosage: b decreasing gradually), possibly in combination with immunosuppressants, chronic eosinophilic pneumonia (Dosage: b decreasing gradually), for the maintenance treatment of chronic forms of sarcoidosis in stages II and III (with dyspnea, cough and deterioration in the lung function) (DS: b)
- preventive treatment of respiratory distress syndrome in preterm infants (DS: b, twice).

Diseases of the upper airways:

- severe forms of hay fever and allergic rhinitis, after failure of nasal sprays containing glucocorticoids (DS: c)
- acute laryngeal and tracheal stenoses: mucosal swelling (angioedema), narrowing laryngitis (pseudo-croup) (DS: b to a).

Skin diseases:

- diseases of the skin and mucous membranes, which due to their severity and / or expansion or visceral involvement can not be treated adequately with local applicable glucocorticoids; these include:
 - allergic and allergic-like reactions, allergic reactions associated with infections: e.g. acute urticaria, shock-like (anaphylactoid) reactions
 - serious skin diseases, partly destroying the skin, drug-induced rash, erythema multiforme, toxic epidermal necrolysis (Lyell's syndrome), pustulosis acuta generalisata, erythema nodosum, acute febrile neutrophilic dermatosis (Sweet's syndrome), allergic contact dermatitis (DS: b to a)

- rash: e.g. related allergic rash such as atopic dermatitis or contact dermatitis, rash caused by pathogens (nummular eczema) (DS: b to a)
- knot forming diseases: e.g. sarcoidosis, inflammation of the lips (granulomatous cheilitis) (DS: b to a)
- severe blistering skin diseases: e.g. pemphigus vulgaris, bullous pemphigoid, benign mucous membrane pemphigoid, linear IgA dermatosis (DS: b to a)
- vasculitis: e.g. allergic vasculitis, polyarteritis nodosa (DS: b to a)
- diseases of the body's immune system (autoimmune diseases) such as: dermatomyositis, systemic scleroderma (indurative phase), chronic discoid and subacute cutaneous lupus erythematosus (DS: b to a)
- severe skin disorders in pregnancy (see also under "Pregnancy and breast-feeding"): e.g. Herpes gestationis, impetigo herpetiformis (DS: d to a)
- severe skin disease with erythema, exfoliation, e.g. pustular psoriasis, pityriasis rubra pilaris, parapsoriasis group (DS: c to a)
- erythroderma, even with Sezary syndrome (DS: c to a)
- other serious 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 (DS: c to a).

Blood diseases / cancers:

- autoimmune diseases of the blood:
anemia due to self-destruction of red blood cells (autoimmune hemolytic anemia) (DS: c to a)
idiopathic thrombocytopenic purpura (Werlhof's disease) (DS: a)
acute phasid decrease number of platelets (intermittent thrombocytopenia) (DS: a)
- malignant diseases such as:
acute lymphoblastic leukemia (DS: e)
Hodgkin's disease (DS: e)
non-Hodgkin's lymphoma (DS: e)
chronic lymphocytic leukemia (DS: e)
Waldenstrom's macroglobulinemia (DS: e)
multiple myeloma (DS: e)
elevated serum calcium levels in malignant underlying disease (DS: c to a)
- prevention and treatment of emesis induced by chemotherapy (DS: b to a)
- palliative therapy in malignant diseases.

Note:

Cutason can be used in advanced cases of malignant diseases for the relief of symptoms such as: loss of appetite, weight loss and general weakness, after other treatment options have been used.

Diseases of the nervous system

- certain forms of paralysis (myasthenia gravis), the 1st choice is azathioprine
- chronic Guillain-Barré syndrome
- Tolosa-Hunt syndrome
- polyneuropathy in monoclonal gammopathy
- multiple sclerosis (for tapering off after high-dose infusion of glucocorticoids in the context of an acute attack)
- some form of epileptic disease in infancy (BNS cramps).

Specific progressive forms of infectious diseases:

- poisoning conditions under serious infectious diseases (in conjunction with antibiotics / chemotherapy), e.g. tuberculous meningitis (DS: b), severe form of pulmonary tuberculosis (DS: b).

Eye diseases (DS: b to a):

- in diseases with ocular involvement and in immunological processes in the eye orbit and eye: disease of the optic nerve (optic neuropathy, e.g. in giant cell arteritis, due to circulation problems or injuries), Behçet syndrome, sarcoidosis, endocrine orbitopathy, apparent swelling of the eye orbit, transplant rejection and certain inflammations of the choroid as Harada's disease and ophthalmia sympathica.

For the following conditions, the administration of Cutason is displayed only after unsuccessful local treatment:

- inflammation of various parts of the eye:

inflammation of the dermis and adjacent tissues, of the cornea or the choroid, chronic inflammation of the chamber water-forming segment of the eye, allergic conjunctivitis, alkali burns, corneal inflammation that occur in the context of an autoimmune disease or syphilis (additional treatment against pathogens required), corneal inflammation caused by Herpes simplex (only by intact corneal surface and under regular ophthalmological control).

Gastrointestinal diseases / liver disease:

- ulcerative colitis (DS: b to c)
- Crohn's disease (DS: b)
- autoimmune disease of the liver (autoimmune hepatitis) (DS: b)
- corrosion of the oesophagus (DS: a).

Kidney disease:

- specific autoimmune disease of the kidneys: Nil disease (minimal change glomerulonephritis) (DS: a), extracapillary-proliferative glomerulonephritis (rapidly progressive glomerulonephritis) (DS: loading doses, usually in combination with cytostatic drugs), in reduction and termination of treatment in Goodpasture's syndrome, long-term continuation of treatment of all other forms (DS: d)
- connective tissue proliferation between the pelvis and kidney arising without identifiable cause (retroperitoneal fibrosis) (DS: b).

2. BEFORE YOU TAKE CUTASON

Do not take Cutason:

- if you are hypersensitive (allergic) to prednisone or any of the other ingredients of Cutason.

Besides allergic reaction, there are no other contraindications during short-term administration of Cutason in acute life-threatening disease situations.

Take special care with Cutason

- if higher doses are needed than in hormone replacement therapy.

Cutason should be used only if your doctor considers it strictly necessary for the following disorders.

Treatment with Cutason 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, specific drugs against the pathogens should be taken simultaneously:

- acute viral infections (hepatitis B, chickenpox, shingles, herpes simplex infections, inflammation of the cornea caused by herpes virus)

- acute and chronic bacterial infections
- fungal diseases with involvement of the internal organs
- certain diseases caused by parasites (amoeba, worm infections); in patients with suspected or confirmed strongyloidiasis, Cutason may lead to the activation and mass propagation of the parasites
- lymph node disease after tuberculosis vaccine (in case of tuberculosis in the medical history, use only with simultaneous take of antituberculars)
- infectious hepatitis (HBsAg-positive chronic active hepatitis)
- poliomyelitis
- 8 weeks before and 2 weeks after immunization with a vaccine containing live germs.

Furthermore, Cutason should be used in the following diseases only if your doctor seems it strictly necessary and if these conditions are simultaneously treated as required:

- gastrointestinal ulcers
- hardly adjustable hypertension
- severe diabetes (diabetes mellitus)
- bone disorders (osteoporosis)
- psychological (mental) illness (also in history), including suicidality; in this case neurological or psychiatric surveillance is recommended;
- increased intraocular pressure (narrow and wide angle glaucoma); ophthalmological monitoring and concomitant therapy is recommended;
- injuries and ulcers of the cornea of the eye; ophthalmological monitoring and concomitant therapy is recommended.

Because of the risk of bowel wall cut with peritonitis, you should take Cutason in the following conditions only if there are compelling medical reasons and under proper supervision:

- severe inflammation of the colon (ulcerative colitis) with impending perforation, with abscess or suppurative inflammation
- inflamed intestinal wall protuberance (diverticulitis)
- after certain intestinal surgery (enteroanastomoses) immediately after the operation.

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 (type of antibiotics) and Cutason are co-administered.

During treatment of a form of muscular paralysis (myasthenia gravis), a symptom deterioration may occur at the beginning, so the adjustment of Cutason should be made in hospital. Especially if the problems in the area of the face and throat are particularly heavy and breathing is impaired, the treatment with Cutason should be started very carefully.

Cutason may mask the signs of infection, complicating the determination of existing or developing infections.

A long-term use, even with small amounts of prednisone, leads to an increased risk of infection, also by such pathogens that otherwise rarely cause infections.

Vaccination with vaccines containing killed pathogens are possible in principle. It should be noted, however, that at high doses of Cutason, the response to the vaccine may be affected.

In long-term treatment with Cutason, regular medical controls (including ophthalmological) are required.

In diabetes, the metabolism should be regularly monitored; a possible increased demand for drugs for the treatment of diabetes (insulin, tablets, etc.) should be considered.

At prolonged treatment with relatively high doses of Cutason, pay particular attention to have a sufficient supply of potassium (e.g., vegetables, bananas) and a limited salt intake. Let the potassium levels in the blood be monitored by a physician.

Serious anaphylactic reactions may occur.

In severe hypertension or severe heart failure you should be carefully monitored by a doctor because of the risk of a deterioration.

If during treatment with Cutason you are exposed to special physical stress, such as febrile illnesses, accidents or surgery, a doctor or an ambulance has to be informed immediately on the ongoing treatment. A temporary increase in the daily dose of Cutason may be necessary.

During long-term treatment with Cutason, your doctor should therefore issue a corticoid-ID card, which you should always carry with you.

Depending on dosage and duration of treatment, a negative effect on calcium metabolism is to be expected, so that a prevention of osteoporosis 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, period after the menopause, and lack of physical activity. Prevention consists in adequate calcium and vitamin D intake, and physical activity. In existing osteoporosis, drug therapy should also be taken in addition.

Upon termination or interruption of long-term intake of Cutason, the following risks should be considered:

recurrence or worsening of the underlying disease, acute sub-function of the adrenal cortex (especially in stressful situations, such as during an infection, after accidents, increased physical stress), by cortisone withdrawal-related signs and symptoms. Viral diseases may occur to be particularly serious in patients treated with Cutason. Particularly at risk are immunocompromised (immuno-suppressed) children and persons who have not had any measles or chickenpox. If these individuals have contact with sick people with measles or chickenpox during treatment with Cutason, they should immediately contact their physician, cause a preventive treatment may be necessary.

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

Talk to your doctor before taking Cutason 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

Because of the risk of growth inhibition, Cutason should be used in children only for compelling medical reasons and their growth should be checked regularly. Therapy with Cutason should be limited in time or alternating (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 should be carefully considered.

Effects of misuse for doping purposes

The use of Cutason can lead to positive results in doping controls. The health consequences of the use of Cutason as a doping agent can not be foreseen, serious health risks can not be excluded.

Taking Cutason with other medicines

Please tell your doctor or pharmacist if you take / use or have recently taken / used other medicines even if they were medicines taken without a prescription.

Which other medicines can affect the effect of Cutason?

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):

- drugs that accelerate the degradation in the liver (barbiturates, phenytoin, carbamazepine, primidone [remedy for seizures], rifampicin [tuberculosis drug]): 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
- certain female sex hormones, e.g. of contraception ("the pill"): the effect of Cutason can be increased
- medicines against excessive production of stomach acid (antacids): 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; in patients with chronic liver disease an increase of the dose of Cutason may be necessary.

How does Cutason affect the action of other medicines?

By concomitant administration of Cutason and

- drugs for cardiac tonus (cardiac glycosides): their effect can be amplified by the possible potassium deficiency caused by Cutason;
- diuretic and laxative medicines (diuretics / laxatives): their potassium excretion effect is enhanced;
- diabetic medicines (antidiabetics / insulin): the hypoglycemic effect may be reduced;
- anticoagulants (oral anticoagulants, coumarin derivatives): their anticoagulant effects can be reduced or enhanced;
- medicines for inflammation and rheumatism (salicylates, indomethacin and other non-steroidal antiinflammatory drugs): the risk of ulcers and gastrointestinal bleeding may be increased;
- certain medicines that can cause muscle relaxation (non-depolarizing muscle relaxants): the relaxation of the muscles can last longer;
- certain drugs from the ophthalmology (atropine) and similarly acting drugs (other anticholinergics): there may be additional increased pressure inside the eye;
- medicines for the treatment of worm diseases (praziquantel): a reduced effect of this agent is possible;
- drugs against malaria or rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine): there is an increased risk of developing myopathy and cardiomyopathy;
- growth hormone (somatropin): its effect is diminished, especially at high doses of Cutason;
- protirelin (a hormone of the midbrain): the rise of the thyroid stimulating hormone (TSH) is reduced;
- immunosuppressant medicines: coadministration of these medicines with Cutason can increase susceptibility to infections and can exacerbate latent infections;
- cyclosporin (medicine used to suppress the body's defense): the cyclosporin levels in the blood are increased; this creates an increased risk of seizures;
- certain drugs to lower blood pressure (ACE inhibitors): increased risk of occurrence of blood dyscrasias;
- fluoroquinolones (a group of antibiotics), can increase the risk of tendon rupture.

Impact on laboratory analysis

Skin reaction in allergy tests may be reduced.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking / using any medicine.

Pregnancy

During pregnancy, this medicine can be taken only with medical advice. Inform your doctor about an existing or actual pregnancy.

During long-term treatment with Cutason during pregnancy, impaired growth of the unborn child can not be excluded.

If Cutason is taken at the end of pregnancy, a regression of the adrenal cortex in the newborn can occur, which may require replacement therapy. Studies in animals have shown side effects in newborns (e.g. cleft palate). An increased risk of oral clefts in humans by administration of glucocorticoids during the first trimester is discussed.

Lactation

Prednisone passes into breast milk. A harm to the infant is not known so far. Nevertheless, the need for administration of Cutason during lactation should be examined carefully. If high doses are needed, you should not breastfeed. Call your doctor immediately.

Effects on ability to drive and use machines

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

Important information about some of the ingredients of Cutason

This medicinal product contains lactose. Please take Cutason only after consulting your doctor if you know that you have an intolerance to some sugars.

3. HOW TO TAKE CUTASON?

- 1) Take Cutason exactly as your doctor has told you.
- 2) Your doctor will decide the dose for you individually.
- 3) Please refer to the prescription information, otherwise Cutason may not work properly.
- 4) Please check with your doctor or pharmacist if you are not sure.

Method of administration

Swallow the tablets whole with plenty of liquid, during or immediately after a meal. 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).

Unless otherwise prescribed by the doctor, the usual dose is:

Hormone replacement therapy (beyond the growth ages)

5 to 7.5 mg prednisone / day, administered in two divided doses (morning and noon, in adrenogenital syndrome morning and evening); if necessary, a mineralcorticoid (fludrocortisone) can be used in addition. In particular physical stresses such as feverish infection, injury, surgery or childbirth, the dose should be increased temporarily as your doctor advises 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 (pharmacotherapy)

The following tables provide an overview of the general dosage guidelines:

BW = Body Weight

1. Adults

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

Dose e) for diseases of the hematopoietic system through special schemes see below.

In general, the total daily dose is taken in the morning between 6.00 and 8.00 a' clock. 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	2 - 3
Average	1 - 2
Maintenance dose	0,25

The lowest possible dose should be used in children.

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

Reduction of the dose

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 duration of treatment depends on the course of the disease. Once a satisfactory treatment result is achieved, the dose is reduced to a maintenance dose or terminated. Your doctor will determine a treatment regimen that you should respect rigorously.

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 can be given over a few days, depending on the underlying disease and the treatment success, can be deducted without tapering off.

In hypothyroidism or liver cirrhosis lower doses may also be sufficient, or a dose reduction may be necessary.

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

Dose e)

Usually prednisone is used as a single dose without tapering required for completing the course. In chemotherapy are well – known e.g. the following regimens:

- non-Hodgkin's 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 is tolerated without complications even in short-term use of higher doses. There are no special measures required. If you notice increased or unusual side effects, you should ask your doctor for advice.

If you forget to take Cutason

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

You can make up for the missing dose during the day and the day after taking the dose prescribed by your doctor as usual.

If you have forgotten to take a dose several times, there may be a recurrence or exacerbation of the disease being treated. In such cases, you should consult your doctor, who will examine the treatment and adjust it if needed.

If you stop taking Cutason

Always follow the dosage regimen prescribed by the physician. Cutason should never be sold without a prescription, in particular because a long - term treatment with Cutason leads to a suppression of the endogenous production of glucocorticoids.

A high physical stress situation can be life threatening (Addisonian crisis).

If you have any questions about taking this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Cutason 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, use of higher doses than in hormone replacement therapy

Depending on dose and duration of treatment, the following side effects can 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 (increase in white blood cells or all blood cells, reduction in certain white blood cells).

Immune system disorders

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

Endocrine disorders

The so-called Cushing's syndrome (typical signs are moon face, central obesity, and flushing), inactivity or atrophy of the adrenal cortex.

Metabolism and nutrition disorders

Weight gain, high blood sugar, diabetes, increased blood lipids (blood cholesterol and triglycerides) and fluid in the tissues, potassium deficiency due to increased potassium excretion, 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

Increase in intraocular pressure (glaucoma), cataract, worsening of corneal ulcers, favoring of inflammations caused by viruses, bacteria or fungi, blurred vision, increased risk of central serous chorioretinopathy (disease of the retina with loss of vision). You should examine your eyes regularly by an ophthalmologist.

Vascular disorders

Hypertension, increased risk for 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

Stretch marks on the skin, thinning of the skin ("parchment skin"), extension of skin vessels, bruising, pitting or bruising, increased body hair, acne, delayed wound healing, inflammatory lesions on the face, especially around the mouth, nose and eyes, changes in skin pigmentation, hypersensitivity reactions, e.g. rash.

Musculoskeletal and connective tissue disorders

Muscle weakness and wasting, bone loss (osteoporosis), are dose-dependent and may also be possible by short-term use, other forms of bone resorption (bone necrosis, head of the humerus and femur), tendinitis, tendon ruptures and epidural lipomatosis, growth inhibition in children.

Note: Too rapid dose reduction after long-term treatment 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 lack of the menstrual cycle (amenorrhea), increase body hair in women (hirsutism), impotence may occur).

General disorders and administration site conditions

Delayed wound healing.

Renal and urinary disorders

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

Cardiac disorders

Slow heart rate.

Countermeasures

Please talk to your doctor or pharmacist if you notice any of the mentioned side effects or other adverse effects during treatment with Cutason.

Do not interrupt the treatment without consulting your doctor.

If gastro-intestinal discomfort, pain in the back, shoulder or hip area, mental upsets, blood sugar conspicuous fluctuations in diabetics or other disturbances occur, inform your doctor immediately.

Please tell your doctor or pharmacist if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE CUTASON?

Keep out of the reach and sight of children.

You should not use this medicine after the expiry date, stated on the blister and on the carton.

Store below 25°C!

6. FURTHER INFORMATION

What Cutason contains

The active substance is Prednisone, an adrenocortical hormone.

1 tablet contains 5 mg prednisone.

The other ingredients are: pregelatinised starch, lactose monohydrate, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, talc.

Content of the pack

Cutason is available in packs of 20 or 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

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Tirana, Albania.

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