PACKAGE LEAFLET: Information for the user

DERMOSOLON

Tablets – 5 mg

(Prednisolone)

Read all of this leaflet carefully before you start taking this medicine, because it contains important information.

- 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 to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects disturbs you or if you notice side effects not listed in this leaflet, please inform your doctor or pharmacist. See section 4.

What is in this leaflet

1. WHAT DERMOSOLON IS AND WHAT IT IS USED FOR

Dermosolon contains the active substance prednisolone which is a glucocorticoid (adrenal cortex hormone) that affects metabolism, electrolyte balance and functioning of tissues.

Dermosolon 5 mg is indicated in diseases which require systemic therapy with glucocorticoids. Depending on the presentation and severity of the disease, these include: (table of **dosages from a to d and dosage e**, see section 3: How to take Dermosolon):

Hormone replacement therapy in:

- impaired adrenal function or insufficiency of adrenal gland of any cause (e.g., Addison's disease, adrenogenital syndrome, surgical removal of adrenal gland (pituitary insufficiency) beyond the growth age (in such cases cortisone and hydrocortisone are the first choice);
- stress disorders caused by long-term corticosteroid therapy.

Rheumatic disorders:

- during active phases of vascular inflammation (dosage: a, b):
  - polyarteritis nodosa (if the patient has hepatitis B, treatment duration should be limited to two weeks);
  - giant cell arteritis, muscle pain and stiffness (polymialgia rheumatica) (dosage: c);
  - inflamation of temporal arteries (arteritis) (dosage: a), in acute visual loss, initial high endovenous loading doses of glucocorticoids are given, and then, chronic treatment is continued keeping under control erythrocyte sedimentation;
- during active phases of rheumatic diseases involving internal organs (dosage: a, b): lupus erythematosus involving internal organs, muscle weakness and pain (polymyositis), cartilage inflamation (polychondritis chronica atrophicans), connective tissue disorders (mixed collagenosis);
- rheumatoid arthritis with rapid and severe progression (dosage: a to d), such as reversible destructive forms (dosage: a) or forms that do not involve articulations (dosage: b);
- other rheumatic disease involving articulations, if the severity of the disease requires this kind of treatment and if certain medicines for treatment of rheumatic diseases (NSAIDs) have not been effective or can not be used*:*
  - inflammation of the vertebral column (spondyloarthritis), inflammation of the vertebral column (ankylosing spondylitis) involving other articulations such as those of the arms and legs (dosage: b, c), psoriasis involving articulations (psoriatic arthritis) (dosage: c, d), gastrointestinal disorders associated with severe inflammation involving articulations (enteropathic artropathy) (dosage: a);
  - arthritis as a result of another existing disease (dosage: c);
  - inflammation of articulations as a result of sarcoidosis (dosage: b at the beginning of therapy);

- severe arthritis of no apparent cause in adolescents (juvenile idiopathic arthritis) which involves internal organs (Still's disease) or the eyes (inflammation of the iris and sorrounding areas) and does not respond to local treatment (dosage: a);
- heart inflammation in rheumatic fever, in severe cases over 2 – 3 months (dosage: a).

Diseases of bronchi and lungs:

- asthma (dosage: c – a), concomitant bronchodilator treatment is recommended;
- acute exacerbation of existing chronic obstructive respiratory airway disease (dosage: b), recommended treatment duration: up to 10 days
- specific lung disease such as: acute inflammation of alveoli (alveolitis) (dosage: b), stiffness and rimodeling of the lung tissue (pulmonary fibrosis) (dosage: b), as maintenance treatment of chronic forms of sarcoidosis in stages II and III (accompanied with dyspnea, cough and pulmonary insufficiency) (dosage: b);
- as preventive treatment of respiratory distress syndrom in preterm infants (dosage: b, repeated twice).

Upper respiratory airways diseases:

- severe forms of drug fever and allergic rhinitis when glucocorticoids given as nasal spray have not been effective (dosage: c);
- acute narrowing of the larynx or trachea: angioedema, obstructive laryngitis (pseudo – croup) (dosage: b to a).

Skin diseases:

- diseases of skin and mucous membranes that due to severity of the disease and / or involvement of certain organs can not be treated locally with glucocorticoids.

These include:

- allergic reactions or reactions similar to them, allergic reactions associated with infections: such as acute urticaria, anaphylactoid reactions;
- severe skin diseases that partially destroy the skin, rash caused by drugs, exudative erythema multiforme, toxic epidermal necrolysis (Lyell's syndrome), pustulosis acuta

generalisata, erythema nodosum, acute neutrophilic dermatosis associated with fever (Sweet's syndrome), allergic contact dermatitis (dosage: b to a);

- rash: e.g., rash caused by an allergic reaction such as atopic dermatitis or contact dermatitis, rash caused by pathogens (nummular eczema) (dosage: b to a);
- diseases associated with presentation of patches on the skin: e.g., sarcoidosis, inflammation of lips (granulomatous cheilitis) (dosage: b to a);
- severe disease associated with presentation of skin blisters: e.g., pemphigus vulgaris, bullous pemphigoid, benign mucous membrane pemphigoid, linerar IgA dermatosis (dosage: b to a);
- vasculitis: e.g., allergic vasculitis, polyarteritis nodosa (dosage: b to a);
- immune system disorders (autoimmune disease): e.g., dermatomyositis, systemic scleroderma (indurative phase), chronic discoid and subacute cutaneous lupus erythematosus (dosage: b to a);
- severe skin diseases during pregnancy (see also "Pregnancy and breast – feeding"): e.g., herpes gestationis, impetigo herpetiformis (dosage: d to a);
- severe skin diseases associated with erythema, skin peeling, e.g, pustular psoriasis, pityriasis rubra pilaris, parapsoriasis group (dosage: c to a); erythroderma, also associated with Sezary syndrome (dosage: c to a);
- other severe diseases: e.g., Jarisch – Herxheimer reaction to penicillin treatment of syphilis, quickly growing cavernous hemangioma, Behçet's disease, pyoderma gangrenosum, eosinophilic fasciitis, lichen planus exanthematicus, inherited epidermolysis bullosa (dosage: c to a).

<u>Blood diseases / Neoplastic diseases:</u>

- autoimmune blood disease:

anemia caused by the destruction of red blood cells by the body itself (autoimmune hemolytic anemia) (dosage: c to a);

idiopathic thrombocytopenic purpura (Werlhof's disease) (dosage: a), acute phase of platelet count decrease (inttermittent thrombocytopenia (dosage: a);

- malign disease, e. g.:

  acute lymphocytic leukemia (dosage: e);

  Hodgkin's disease (dosage: e);

non-Hodkgin’s lymphoma (dosage: e);
chronic lymphocytic leukemia (dosage: e);
Waldenstrom's macroglobulinemia (dosage: e);
multiple myeloma (dosage: e);
high blood calcium levels as a result of an existing malignant disease (dosage: c to a);

- prevention and treatment of vomiting due to chemotherapy (dosage: b to a).

Note:

Dermosolon 5 mg may be used in the advanced stages of malignant disease for the relief of symptoms such as loss of apetite, loss of weight and general weakness, when other specific treatment options have not been successful.

Central nervous system disease (dosage: a)

- certain forms of paralysis (myasthenia gravis), azathioprine is the first choice, chronic Gullain-Barré syndrome, Tolosa-Hunt syndrome, polyneuropathy as a result of monoclonal gammopathy, multiple sclerosis (for gradual decrease of dose after administration of perfusions with high glucocorticoid doses for the treatment of an acute atack), certain epileptic forms in infants (BNS cramps).

Specific progressive forms of infectious diseases:

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

Eye diseases (dosage: b to a):

- diseases and inflamatory processes that involve the eye and the orbit of the eye: diseases that involve the optic nerve (optic neuropathy, e.g., giant cell arteritis due to problems of blood circulation or injuries), Behçet’s syndrome, sarcoidosis, endocrine orbitopathy, visible swelling of the orbit, transplant rejection reaction and certain choroid diseases such as Harada disease and sympathetic ophtalmia.

In the following diseases, Dermosolon may be used only when local treatment has not been effective:

- inflammation of different parts of the eye:

inflammation of the dermis and the tissues sorrounding the eye, inflammation of cornea or choroid, chronic inflammation of the chamber responsible for formation of the liquid in the eye, allergic conjunctivitis, burns from alkaline substances, inflammation of cornea due to autoimmune disease or syphilis (in such case, additional treatment against the pathogen is necessary), inflammation of cornea caused by Herpes simplex (only when the surface of cornea is unharmed and under strict ophtalmological control).

Gastrointestinal disorder / liver disease:

- colitis ulecerosa (dosage: b to c);
- Crohn's disease (dosage: b);
- autoimmune liver disease (autoimmune hepatitis) (dosage: b);
- corrosion of the esophagus (dosage: a).

Kidney disease

- Kidney autoimmune disease: glomerulonephritis with minimal change (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, for continuation of long – term treatment of all other forms (dosage: d);
- spread of connective tissue in the area between kidneys and pelvis with no defined cause (retroperitoneal fibrosis) (dosage: b).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DERMOSOLON

Do not take Dermosolon:

- if you are hypersensitive (allergic) to prednisolone or to any of the excipients of Dermosolon mentioned in section 6.

During short-term treatment with Dermosolon of life-threatening diseases, there are no other contraindications (except hypersensitivity reactions mentioned above).

Take special care with Dermosolon

Please talk to your doctor or pharmacist before you take Dermosolon.

Take special care with Dermosolon 5 mg:

- if higher doses than those used in the hormone replacing therapy are needed; in the following diseases, Dermosolon should be used only if your doctor deems it necessary; treatment with Dermosolon can lead to an increased risk of bacterial, viral, parasitic, opportunistic and fungal infections by suppressing the body's immune system; the signs and symptoms of an existing or developing infection can be masked and difficult to see; latent infections such as tuberculosis or hepatitis B can reactivate; if one of the following diseases is present at the same time, it may also be necessary to take specific drugs against the pathogens;
- in acute viral infections (hepatitis B, varicella, herpes zoster infections, herpes simplex infections, inflammation of cornea caused by herpes virus);
- in acute and chronic bacterial infections;
- in mycotic infections (caused by fungi) involving internal organs;
- in several diseases caused by parasites (amebas, worm infections); in patients with suspected or confirmed infection with dwarf thread worms (strongyloides), Dermosolon can activate and mass multiply the parasites;
- in lymph node diseases due to tuberculosis vaccine (if the patient has had tuberculosis, concomitant treatment with antituberculosis medicines is necessary);
- in infective hepatitis (HbsAg-positive, chronic, active hepatitis);
- in poliomyelitis;
- 8 weeks before and 2 weeks after vaccination with a vaccine of live microorganisms.

Additionally, Dermosolon may be used in the following diseases, only if your doctor deems it necessary and if these diseases are treated concomitantly with the required additional therapy:

- gastrointestinal ulcers;
- hypertension that is difficult to control;
- severe diabetes (diabetes mellitus);
- bone disorders (osteoporosis);
- current or previous mental disease, including suicidal risk; in this case, neurological or psychiatric monitoring is recommended;

- increase of intraocular pressure (wide or narrow angle glaucoma); ophthalmological supervision and concomitant therapy are recommended;
- ulcers or damages of eye cornea; ophthalmological supervision and concomitant therapy are recommended.

Because of the risk of intestine wall perforation (which could lead to peritonitis), Dermosolon may be used in the following diseases only if there is a strong medical reason and under continuous monitoring:

- severe inflammation of the colon (ulcerative colitis) associated with perforation, abscess or accumulation of pus, possibly without irritation of the peritoneum;
- inflammed mass in the intestine wall (diverticulitis);
- after several surgical interventions (enteroanastomosis), immediately after surgery.

If you experience blurred vision or other visual disturbances, contact your doctor.
The signs of peritoneal irritation following a gastrointestinal ulcer may be absent in patients receiving high doses of glucocorticoids.
The risk of tendon discomfort, tendinitis, and tendon rupture is increased when fluoroquinolones (certain antibiotics) and Dermosolon are given together.

In the beginning of treatment of myasthenia gravis with Dermosolon, a deterioration of the condition may occur. In such case, dose should be adjusted in hospital. Particular caution should be exerted in the beginning of treatment with Dermosolon, if the patient presents with severe problems in the area of face, throat and respiratory insufficiency.

Treatment with Dermosolon may mask the signs of an infection, making it difficult to diagnose. Long-term treatment with prednisolone, even that with small doses, may increase the risk of an infection including pathogenic organisms, which would otherwise rarely cause infections.

Vaccination with dead pathogenic microrganisms is possible. However, it should be noted that high doses of Dermosolon may affect patient’s response to the vaccine.

During long-term treatment with Dermosolon, the patient should undergo regular medical examinations (ocular examination included).

In diabetic patients, an increase in the dose of antidiabetic medicines may be necessary (insuline, oral tablets, etc.). These patients should undergo regular medical examinations to maintain their metabolism under control.
During long-term treatment with high doses of Dermosolon, care should be taken to receive adequate supply of potassium (e.g., vegetables, bananas) and reduce the amount of salt.
Potassium level in the body should be monitored by the doctor.

Severe anaphylactic reactions (overreaction of the immune system) can occur.
If you have severe hypertension or severe cardiac insufficiency, you should make regular visits to the doctor, because deterioration of the condition may occur.

If during treatment with Dermosolon, you get a disease associated with fever, have an accident or undergo a surgical intervention, give birth etc., you should immediately inform your doctor or your medical center for the treatment in question. A temporary increase of the daily dose of Dermosolon may be necessary.
If treatment with Dermosolon continues for a long period, your doctor should provide you with a specific card, which you should always carry with you.

Given that, depending on the dose and duration of treatment, disorders of calcium metabolism may occur, measures on prevention of osteoporosis should be taken. This may in particular happen in patients with certain risk factors such as: familial heredity, advanced age, insufficent intake of calcium and proteins, smoking, excess alcohol consumption, being postmenopause and lack of physical activity. In order to prevent these disorders, an adequate amount of calcium and vitamin D should be taken and physical activity should be done. In case of existing osteoporosis, an additional, appropriate therapy should be taken.
After interruption or completion of long-term treatment with Dermosolon, the following risks should be considered:

recurrence or deterioration of the existing disease, acute insufficiency of the adrenal gland (particularly when the organism is in stress, e.g., during an infection, after an accident or increased physical stress), signs or symptoms as a result of interruption of corticosteroid therapy.

Viral diseases (e.g. measles, chickenpox) can be particularly severe in patients treated with Dermosolon. Children with immune system disorders (weakened immune system) or patients with no previous chickenpox or measles infection are particularly at risk. If, during treatment with Dermosolon, these individuals have contact with individuals with measles or chicken pox infection, they should contact their doctor immediately. In such cases a preventive treatment may be necessary.

Talk to your doctor before taking Dermosolon 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.

Impact on laboratory tests:
Skin reaction to allergy test may be reduced.
The use of Dermosolon can lead to positive results in doping tests.

Children and adolescents
Given that Dermosolon treatment may inhibit growth, this medicine should be used only if the doctor deems it necessary and growth of the child should be continuously monitored. Therapy with Dermosolon should be administered for a limited time or alternately (e.g. every other day, but then with a double dose (alternating therapy)).

Elderly
As elderly patients have an increased risk of osteoporosis, the risk-benefit ratio of therapy with Dermosolon should be carefully considered.

Other medicines and Dermosolon

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or are planning to take / use any other medicines including medicines without prescription.

Which medicines may influence the efficacy of Dermosolon?

- Medicines that enhance metabolization by the liver (barbiturates, phenytoin, primidone [for treatment of convulsions], rifampicin [for treatment of tuberculosis]): the efficacy of Dermosolon may decrease.
- Ephedrine (can be contained for example in drugs against hypotension, chronic bronchitis, asthma attacks and to reduce swelling of the mucous membranes in case of colds and as a component of appetite suppressants): the accelerated breakdown in the body can reduce the effectiveness of Dermosolon.
- Medicines that slow down the breakdown in the liver, such as certain medicines for fungal infections (ketoconazole, itraconazole), can increase the effect of Dermosolon.
- Some medicines can increase the effects of Dermosolon and your doctor may want to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- Several female sexual hormones, e.g., contraceptives: the efficacy of Dermosolon may increase.
- Medicines that work against excess gastric acid production (antacids): with simultaneous administration of magnesium or aluminum hydroxide, a reduced absorption of prednisolone is possible. The intake of the two drugs should therefore take place at intervals (2 hours).

How does Dermosolon influence other medicine's effect?

Taking Dermosolon concomitantly with:

- medicines that affect the cardiac tonus (cardiac glycosides): because Dermosolon may cause potassium deficiency in the body, the effect of these medicines may increase;
- diuretics and laxatives: these medicines' effect on potassium excretion is increased;
- medicines that treat diabetes (antidiabetics / insuline): the hypoglycemic effect may decrease;

- anticoagulants (oral anticoagulants, coumarine derivatives): their effect may decrease or increase; your doctor will decide whether it is necessary to adjust the dose of the anticoagulant medicine;
- medicines against inflammation and rheumatism (salicylates, indomethacine and other nonsteroidal anti – inflammatory medicines): the risk of peptic ulcer and gastrointestinal bleeding may increase;
- several medicines that cause muscle relaxation: (non – depolarising muscle relaxants): muscle relaxation may last longer;
- several ophtalmic medicines (atropine) and medicines acting alike (other anticholinergics): further increase of intraocular pressure may occur;
- medicines for the treatment of diseases caused by worms (praziquantel): efficacy of this medicine may decrease;
- medicines for treatment of malaria and rheumatic disease (chloroquine, hydroxychloroquine, mefloquine): increased risk of myopathy and cardiomyopathy;
- growth hormone (somatotropin): particularly high doses of Dermosolon may decrease the efficacy of this medicine;
- protirelin (a hormone of midbrain): the increase of thyroid stimulating hormone (TSH) is inhibited;
- Dermosolon and the simultaneous use of drugs to suppress the body's immune system (immunosuppressive substances) can increase the susceptibility to infections and worsen existing but perhaps not yet manifested infections;
- in addition for cyclosporin (used to inhibit body’s immune system): cyclosporin blood levels increase; this may lead to increased risk of convulsions;
- several medicines that are used to lower blood pressure (ACE inhibitors): the risk of blood dyscrasias is increased;
- fluoroquinolones, a specific group of antibiotics, can increase the risk of tendon rupture.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you might be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

This medicine may be taken durig pregnancy only with doctor's prescription. Inform your doctor if you are pregnant.

Disorders of the fetus growth may not be excluded during long – term treatment with Dermosolon in pregnancy.

If Dermosolon is taken at the end of pregnancy, adrenal gland insufficiency may occur in the newborn, which may require a gradual replacement therapy. Prednisolone showed teratogenic effects in animal experiments (e.g. cleft palate). An increased risk of such damage in humans through the administration of prednisolone during the first three months of pregnancy is discussed.

Breastfeeding

Prednisolone appears in breast milk. Cases of harm to the infant are not known until now. However, the need of administering Dermosolon during breastfeeding should be carefully evaluated. You should not breastfeed your child, if high doses are needed.

Consult your doctor or pharmacist before taking / using any medicine.

Driving and using machines

Until now there is no evidence that Dermosolon affects the ability to drive or operate machines. This applies also to individuals who work without a secure hold.

Important information about some of the excipients of Dermosolon

This medicine contains lactose. If you have a known intolerance to some sugars, contact your doctor before taking Dermosolon.

3. HOW TO TAKE DERMOSOLON

1. Always take Dermosolon according to your doctor's instructions.
2. The dose is determined individually for you by the doctor.
3. Follow the instructions of use; otherwise Dermosolon may not exhibit the expected effect.
4. Ask your doctor / pharmacist if you are not sure.

Method of administration

Take the whole tablet with a sufficient quantity of liquid, during or immediately after a meal.
Hormone replacement therapy in chronic adrenal gland insufficiency is a lifelong therapy.
The possibility of treatment every 2 days should be tested by the doctor depending on the disease and individual response to the therapy.

If not prescribed otherwise by the doctor, the usual dose is:

Hormone replacement therapy (beyond the growth age):

5 to 7.5 mg prednisolone / day, divided in two doses (in the morning and lunch time, in androgenital syndrome in the morning and dinner time); if needed, a mineralocorticoid (fludrocortisone) may be added. In stressful physical conditions such as infections with fever, accidents, surgery or childbirth, the dose is increased temporarily upon doctor's recommendation.
Stressful conditions after a long-term treatment with glucocorticoids: intially up to 50 mg prednisolone / day.
The dose is gradually decreased during several days.

Treatment of specific diseases (pharmacotherapy):

The tables below present a summary of the general dosage guidelines:

1. Adults

Dosage	Dose in mg/day	Dose in mg/kg/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)	---

For dose e) in blood diseases, see the special scheme below.

In general, the total daily dose is taken early in the morning between 6.00 and 8.00 o'clock. High daily doses, depending on the disease, can also be divided to 2 - 4 doses, and average daily doses may be dividided in 2 - 3 separate doses.

2. Children

Dosage	Dose in mg/kg/day
High dose	2 - 3
Average dose	1 - 2
Maintenance dose	0,25

In children, the lowest possible doses should be used. In special cases (e.g. BNS cramps) deviations from this recommendation may be possible.

Dose reduction

After achieving the desired effect, and depending on the underlying disease, the reduction of the dose should begin.

If the daily dose is divided to several doses, the evening dose is reduced first and then the lunchtime dose, if there is any.

After that, the dose is reduced in larger steps, and below a dose of approximately 30 mg / day, the reduction should be in smaller steps.

The duration of treatment depends on the disease's course. When a satisfactory result is achieved from treatment, the dose is reduced to the maintenance dose or the treatment is discontinued. The doctor will determine a dosage regimen, which you should strictly follow.

While observing the disease activity, the following steps can serve as a guide for reducing the dose:

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,
less than 6 mg / day	reduction by 0.5 mg	every 4 - 8 weeks.

High doses, which are used for a few days, may be discontinued without gradual reduction depending on the disease and the results of treatment.

In hypothyroidism or liver cirrhosis lower doses may be sufficient or dosage reduction may be necessary.

Dosage e)
As a rule, prednisolone is used as a single dose, with no need of gradual reduction at the end of treatment. In chemotherapy, dosage regimens such as the following are known:

- non-Hodgkin-lymphoma: CHOP-regimen, 100 mg / m² prednisolone in days 1 - 5, COP-regimen 100 mg / m², prednisolone in days 1 – 5;
- chronic lymphocytic leukemia: Knospe regimen, prednisolone 75 / 50 / 25 mg in days 1 – 3;
- Hodgkin's disease: COPP-ABVD-regimen, 40 mg / m² prednisolone in days 1 - 14.
- multiple myeloma: Alexanian-regimen, 2 mg /kg prednisolone in days 1 - 4.

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

If you take more Dermosolon than you should
Usually, Dermosolon is well - tolerated even when high doses are taken for a short period. No special measures are necessary. If you notice severe or unusual side effects, consult your doctor.

If you forget to take Dermosolon
You may take the forgotten dose later during the day and the next day you should take the usual dose that the doctor has recommended.
If you continuously forget to take the doses, you may, among other things, have reappearance or worsening of the disease being treated.
In such cases you should contact your doctor, who will review the treatment and adjust it if necessary.

If you stop taking Dermosolon

Strictly follow the dosage regimen your doctor has determined for you. Dermosolon should never be discontinued without the doctor's approval, because, long-term treatment with Dermosolon in particular, causes a decrease of endogenous glucocorticoid production. In such cases, a situation with unusual physical stress may be life-threatening (Addisonian crisis).

If you have other questions regarding the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. For the evaluation of side effects the following indicators of frequency are used:

Very frequent	More than 1 patient in 10
Frequent	1 to 10 patients in 100
Unusual	1 to 10 patients in 1.000
Rare	1 to 10 patients in 10.000
Very rare	Less than 1 patient in 10.000
Unknown	Frequency cannot be determined based on available data

Possible effects

Hormone replacement therapy

Risk of side effects is low if the recommended doses are used.

When for the treatment of several diseases, higher doses than those in the hormone replacement therapy are used, the following side effects may occur depending on the treatment duration and dose and their frequency can therefore not be specified here:

Infections and infestations

Masking of infections, manifestation, exacerbation or reactivation of viral, fungal, bacterial infections, as well as parasitic or opportunistic infections, activation of dwarf threadworm infection.

Blood and lymphatic system disorders

Changes in blood formula (increase in white blood cells or other blood cells, decrease in certain white blood cells).

Immune system disorders

Hypersensitivity reactions (e.g. drug eruption), severe anaphylactic reactions such as irregular heartbeat; bronchospasm (spasms of the smooth bronchial muscles), too high or too low blood pressure, circulatory collapse, cardiac arrest, weakening of the immune system.

Endocrine disorders

Induction of Cushing syndrome (typical signs are facies lunata, truncal obesity and flushing of face), dysfunction of adrenal glands, growth retardation in children.

Metabolism and nutrition disorders

Weight gain, high blood sugar, diabetes, increase of blood lipids (cholesterol and triglycerides) and water retention in tissues, potassium deficiency due to increased potassium excretion, increased appetite.

Psychiatric disorders

Depression, irritability, euphoria, psychosis, mania, hallucinations, mood lability, anxiety, suicidal risk, sleep disorders.

Nervous system disorders

Increased intracranial pressure (particularly in children), manifestation of previously unrecognised epilepsy and increase of susceptibility to existing epilepsy.

Eye disorders

Increase of intraocular pressure (glaucoma), cataract, worsening of corneal ulcers, favoring of viral, fungal or bacterial infections of the eye, blurred vision.
During systemic treatment with corticoids, there may be an increased risk of water retention under retina with a risk of retinal detachment (central, serous chorioretinopathy).

Cardiac disorders

Not known: slow heart rate.

Vascular disorders

Increased arterial pressure, increased risk of artherosclerosis and trombosis, vasculitis (also as withdrawal symptom after long-term therapy), increased vascular fragility.

Gastro-intestinal tract disorders

Gastrointestinal ulcer, gastrointestinal bleeding, pancreatitis.

Skin and subcutaneous tissue disorders

Striae, thinning of skin, dilation of blood vessels of the skin, tendency to bruise, ecchymoses or red spots, increased body hair, acne, inflammatory changes of the face skin, particularly in the mouth, nose and eyes, changes in skin pigmentation, hypersensitivity reactions, such as skin rash.

Musculoskeletal and connective tissue disorders

Muscle weakness and dystrophy, myopathy, weakening of the bones (osteoporosis) occur depending on the dose and are possible even after a short – term use, other forms of bone weakening (necrosis of the head of femur and humerus), tendon discomfort, tendinitis, tendon ruptures, temporary fat deposits in various parts of the body, e.g. in the spinal canal (epidural) or chest (epicardial, mediastinal).

Note: if after a long-term treatment, the dose reduction is too rapid, muscle and joint pain may occur.

Reproductive system and breast disorders

Disorders of the sexual hormone secretion (as a result of which absence of the menstrual cycle (amenorrhea), male body hair in women (hirsutism), impotence occur).

General disorders and administration site conditions

Prolonged 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.

Special instructions:

Talk to your doctor or pharmacist if you notice any of the side effects mentioned above or other unwanted side effects during treatment with Dermosolon. Never discontinue the treatment by yourself.

Immediately inform your doctor if gastrointestinal disturbances, pain in the back, shoulders or hips, psychic disturbances, apparent changes of blood sugar level in diabetics or other disturbances occur.

If any of the side effects disturbs you or if you notice side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE DERMOSOLON

Keep this medicine out of the sight and reach of children!

Do not store above 25°C!

Do not use this medicine after the expiry date which is stated on the carton box.

6. OTHER INFORMATION

What Dermosolon contains

The **active substance** is prednisolone.

Each tablet contains 5 mg prednisolone.

The **excipients** are: pregelatinized starch, lactose monohydrate, colloidal anhydrous silica, sodium starch glycolate, magnesium stearate.

Contents of the pack

Carton box with 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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