Package leaflet: Information for the patient

Prednisolon F 2 mg tablets
Dexamethasone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prednisolon F is and what it is used for

Prednisolone F tablets contain the active substance dexamethasone. It is a synthetic glucocorticoid (adrenal hormone) that affects metabolism, electrolyte balance and tissue functions. Dexamethasone has a strong anti-inflammatory and anti-allergic action, which has a favorable effect on a number of diseases and conditions that are due to inflammation and allergy.

Prednisolone F is used in diseases that require systemic glucocorticoid therapy. These include, depending on the type and severity:

Neurological diseases
- Brain oedema caused by brain tumor, neurosurgical interventions, bacterial inflammation of the brain envelopes (meningitis), cerebral abscess.

Pulmonary and respiratory diseases
- Exacerbation of asthma.

Skin diseases
- Initial treatment of extensive, severe, acute skin diseases such as erythroderma, pemphigus vulgaris, acute eczema.

Autoimmune / rheumatic diseases
- Initial treatment of autoimmune diseases, such as systemic lupus erythematosus (especially when affected by internal organs).

- Severe progressive form of active rheumatoid arthritis (e.g. forms that lead to rapid destruction of joints and / or tissues outside the joints).
- Severe systemic juvenile idiopathic arthritis.

Hematological diseases
- Diseases of the blood (e.g. idiopathic thrombocytopenic purpura in adults).

Infectious diseases
- Severe infectious diseases with toxic conditions (e.g. tuberculosis, typhus), only in combination with appropriate anti-infectious treatment).

Endocrine diseases
- Hormone replacement therapy for reduced adrenal function or impaired adrenal function (adult adrenogenital syndrome) (applies to Prednisolone F 0.5 mg).

Oncological diseases
- Palliative treatment of malignancies.
- Treatment of some malignancies (e.g. symptomatic multiple myeloma, acute lymphoblastic leukemia, Hodgkin's disease and non-Hodgkin's lymphoma) in combination with other medicinal products.
- Prophylaxis and treatment of postoperative or cytotoxic vomiting.

2. What you need to know before you use Prednisolon F

Do not use Prednisolon F
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)
- if you have an infection affecting the whole body (unless undergoing antibacterial treatment)
- if you are going to have a vaccination by live vaccines

Warnings and precautions
Talk to your doctor or pharmacist before using Prednisolon F.
Treatment with glucocorticoids may lead to reduced activity of the adrenal cortex (insufficient glucocorticoid formation by the body). Depending on the dose and duration of treatment, this may persist for several months, and in some cases more than one year after stopping of treatment. If you are experiencing particular physical stress during treatment with glucocorticoids (such as fever, trauma or surgery, childbirth, etc.), you should tell your doctor about current treatment. A temporary increase in the daily dose of Prednisolone F may be necessary. Even in the case of prolonged reduced adrenal cortex activity after the end of treatment, glucocorticoid use may be necessary in stressful physical situations.

To avoid the development of acute treatment-related adrenal insufficiency, your doctor will prescribe a dose reduction plan upon discontinuation of treatment, which you should strictly follow.

By suppressing the immune system of the body, treatment with Prednisolone F can lead to an increased risk of developing bacterial, viral, parasitic, fungal infections. It can mask the signs and symptoms of an existing or developing infection, making it difficult to recognize them.

For the following diseases, Prednisolone F should only be started if your doctor thinks this is absolutely necessary:
- Acute viral infections (varicella, herpes zoster, herpes simplex, corneal inflammation of the eye caused by herpes viruses);
- HbsAg-positive chronic active hepatitis (infectious liver inflammation);
- About 8 weeks before and up to 2 weeks after vaccination with live vaccines;
- Fungal and parasitic infections affecting internal organs;
- Some diseases caused by parasites. In patients with suspected or confirmed infection with roundworms (nematodes), glucocorticoids may cause activation and mass spread of these parasites;
- Poliomyelitis;
- Inflammation of lymph nodes after vaccination for tuberculosis;
- Acute and chronic bacterial infections;
- In confirmed tuberculosis, it should only be used together with medicines to treat tuberculosis.

The following diseases should be specifically observed during concomitant treatment with Prednisolone F tablets and treated according to clinical needs:
- Gastrointestinal ulcers;
- Bone loss (osteoporosis);
- Severe heart failure;
- Poorly controlled high blood pressure
- Poorly controlled diabetes mellitus;
- Mental illness (current or past), incl. suicidal tendency. In this case, neurological or psychiatric monitoring is recommended;
- Increased intraocular pressure (closed-angle and open-angle glaucoma). Ophthalmic monitoring and additional treatment are recommended;
- Injuries and corneal ulceration. Ophthalmic monitoring and additional treatment are recommended.

Due to the risk of intestinal rupture (perforation), Prednisolone F can only be taken if there are convincing medical reasons and under appropriate supervision:
- for severe inflammation of the colon (ulcerative colitis);
- inflammatory bowel enlargement (diverticulitis);
- after some intestinal operations (enteroenterostomy), immediately after surgery.

Signs of peritoneal irritation (a characteristic pain syndrome in inflammation of the serous envelope covering the abdominal cavity and internal organs) after gastrointestinal perforation may be absent in patients receiving high doses of corticosteroids.

In diabetic patients, blood glucose levels should be checked regularly. Consideration should be given to the need to increase the dose of medicines to treat diabetes (insulin, oral antidiabetic agents).

Patients with severe hypertension and / or severe heart failure should be closely monitored due to the risk of deterioration.

High doses may lead to slow heart rhythm.

Severe anaphylactic reactions (severe life-threatening allergic reactions) may occur.

There is an increased risk of tendon disorder, inflammation and rupture when dexamethasone is co-administered with certain antibiotics (fluoroquinolones).

During treatment of myasthenia gravis (a form of muscle paralysis), the symptoms may get worse at the beginning.

Long-term use, even with small doses of dexamethasone, leads to an increased risk of infections, even from such micro-organisms that would otherwise rarely cause infections (opportunistic infections). At the same time, the signs of infection can be masked, making it more difficult to diagnose an existing or developing infection.

Vaccination with killed vaccines (inactivated vaccines) is usually possible. However, it should be noted that the immune response and hence the efficacy of the vaccine can be compromised by higher doses of corticosteroids.

Long-term treatment with Prednisolone F requires regular medical (including ophthalmic) examinations.

Particularly during prolonged treatment with high doses of Prednisolone F, sufficient calcium intake and limited intake of salt should be ensured. The doctor will monitor the potassium values in your blood.

Depending on the dose and duration of treatment, a negative effect on calcium metabolism can be expected. Therefore, prevention of osteoporosis is recommended. This is particularly true for patients with concomitant risk factors such as family predisposition, elderly, insufficient protein and calcium intake, heavy smoking, excessive alcohol consumption, post-menopause and lack of physical activity. Prophylaxis consists of adequate intake of calcium and vitamin D and physical activity. With already existing osteoporosis, your doctor may also consider taking medication.

The following risks should be considered when discontinuing long-term glucocorticoid use: reoccurrence or worsening of the underlying disease, acute adrenal insufficiency, cortisone withdrawal syndrome.

Certain viral diseases (eg chickenpox, measles) may be severe in patients treated with glucocorticoids. Patients with impaired immunity who have not yet had measles or varicella are particularly at risk. If these patients get in contact with people infected with measles or varicella while being treated with dexamethasone, they should immediately contact their doctor who will, if necessary, include preventive treatment.

Symptoms of tumor decay syndrome such as muscle cramps, muscle weakness, confusion, loss of vision or visual disturbances and shortness of breath have been observed in patients with malignant haematological conditions after use of dexamethasone alone or in combination with other chemotherapeutic agents.

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

Children and adolescents

Because of the risk of growth inhibition, Prednisolone F should only be used in children for convincing medical reasons, and in prolonged treatment, growth should be monitored regularly. Treatment with Prednisolone F should be used for a limited duration or at an alternate regimen (eg a double dose every other day).
Dexamethasone should not be routinely used in preterm infants with respiratory problems.

Elderly
In elderly patients, a special benefit / risk assessment should also be made due to the increased risk of osteoporosis.

Doping tests
The use of dexamethasone may result in positive results in doping control tests.

Other medicines and Prednisolon F
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

What other medicines can affect the effect of Prednisolon F?
- Medicines that accelerate breakdown in the liver such as some sedative medications (barbiturates), medicines used to treat seizures (phenytoin, carbamazepine, primidone) and some medicines for the treatment of tuberculosis (rifampicin) may reduce the effect of corticosteroids.
- Some medicines can increase the effects of dexamethasone and your doctor may think you need more careful monitoring if you are taking these medicines (such as some AIDS medicines: ritonavir, cobicistat).
- Medicines that delay degradation in the liver, such as some medicines to treat fungal infections (ketoconazole, itraconazole), may increase the effect of corticosteroids.
- Some female sex hormones, e.g. to prevent contraception (oral contraceptives): the effect of dexamethasone may be increased.

- Medicines used to treat increased gastric acid (antacids): Concomitant administration of magnesium hydroxide or aluminum hydroxide may lead to decreased absorption of dexamethasone. There should be an interval of 2 hours between taking both medicines.
- Efedrine (eg, medicines for low blood pressure, chronic bronchitis, asthma attacks, medicines which suppress mucosal edema in rhinitis and appetite suppressants may contain ephedrine): Dexamethasone potency may be reduced by accelerated degradation in the body.

How can Prednisolon F affect other medicines?
- When used concomitantly with certain blood pressure lowering medicines (ACE inhibitors), dexamethasone may increase the risk of changes in blood count.
- Dexamethasone may increase the effect of heart-strengthening medicines (cardiac glycosides) by lowering potassium in the blood.
- Dexamethasone may increase the effect of diuretics (saluretics) or purgatives (laxatives) on potassium excretion.
- Dexamethasone may reduce the blood glucose lowering effect of oral antidiabetic agents and insulin.
- Dexamethasone may weaken or increase the effects of medicines that reduce blood clotting (coumarin oral anticoagulants). Your doctor will decide whether anticoagulant dose adjustment is necessary.

- With concomitant use with anti-inflammatory and anti-rheumatic agents (salicylates, indomethacin and other non-steroidal anti-inflammatory drugs), dexamethasone may increase the risk of gastric ulceration and gastrointestinal bleeding.
- Dexamethasone may prolong the muscle relaxing effect of some medicines (nondepolarizing muscle relaxants).
- Dexamethasone may potentiate the intraocular pressure-increasing effects of certain drugs (atropine and other anticholinergics).
- Dexamethasone may reduce the effect of medicines to treat parasitic infections (amoebas, worms) (praziquantel).
- With concomitant use of medicines for malaria and rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine), dexamethasone may increase the risk of muscle disorders or heart muscle disease (myopathies, cardiomyopathies).
- Dexamethasone may reduce the effect of growth hormones (somatotropin), especially if used in high doses and for a long time.
- Dexamethasone may reduce thyroid stimulating hormone (TSH) when protirelin is given.
- If used with medicines that suppress the body's immune system (immunosuppressants), dexamethasone may increase the likelihood of development of infections and worsen existing infections that have not yet been manifested.
- In addition to ciclosporin (a medicine used to suppress the body's immune system): dexamethasone may increase the blood cyclosporin concentration and hence the risk of seizures.
- Co-administration with fluoroquinolones (a group of antibiotics) may increase the risk of tendon damage.

Effect on tests
Glucocorticoids can suppress skin reactions in skin allergy tests.

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

Pregnancy
Dexamethasone passes through the placenta. During pregnancy, especially during the first trimester, it should only be used after a careful benefit-risk assessment.
Long-term treatment with glucocorticoids during pregnancy cannot exclude disturbances in the growth of the fetus. If glucocorticoids are administered at the end of pregnancy, there is a risk of reduced adrenal function in the newborn, which may require replacement therapy, which should be slowly reduced.

Breastfeeding
Glucocorticoids, incl. dexamethasone may pass into breast milk. A risk to the newborns/infants cannot be excluded. A decision on whether to continue/discontinue breast feeding or to continue/ discontinue therapy with dexamethasone should be made taking into account the benefit of breast feeding to the child and the benefit of dexamethasone therapy to the woman.

Driving and using machines
There is no evidence of adverse effects of dexamethasone on the ability to drive or use machines.

Prednisolone F contains lactose
This product contains lactose (milk sugar) as an excipient and is therefore unsuitable for people with congenital or acquired intolerance to some sugars. If you have been told by your doctor that you have such intolerance, consult with your doctor before taking this product.

3. How to use Prednisolon F

Always take this medicine exactly as your doctor has told you! Your doctor will determine your dose individually. Please follow the instructions to get the right effect of Prednisolone F. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual doses are:

- Brain edema: 16-24 mg (up to 48 mg) orally divided into 3-4 (up to 6) single doses for 4-8 days. For this indication, tablets of higher strength are preferred.
- Brain edema due to bacterial meningitis: 0.15 mg / kg body weight every 6 hours for 4 days; in children: 0.4 mg / kg body weight every 12 hours for 2 days, starting before the first antibiotics are administered.
- Severe acute asthma attack: 8-20 mg adults, then 8 mg every 4 hours if needed.
  Children: 0.15-0.3 mg / kg body weight.
- Acute skin diseases: Depending on the nature and severity of the disease, daily doses of 8-40 mg, in individual cases up to 100 mg, followed by dose-lowering therapy, are administered.
  Systemic lupus erythematosus: 6-16 mg / day.
- Severe progressive form of active rheumatoid arthritis (for example, forms that cause rapid joint and / or tissue destruction): 12-16 mg / day, in extra-joint manifestations 6-12 mg / day.
- Diseases of the blood (eg idiopathic thrombocytopenic purpura in adults): 40 mg / day for 4 days in cycles.
- Severe infectious diseases with toxic conditions (eg tuberculosis, typhus): 4-20 mg / day for a few days, only together with concomitant anti-infective therapy.
- Congenital adrenogenital syndrome in adults: 0.25-0.75 mg / day as a single dose. If necessary, supplemental intake of mineralocorticoid (fludrocortisone) is added. In case of particular physical stress (e.g. trauma, surgery), intercurrent infections, etc., a 2 to 3-fold increase in the dose may be required, and in extreme stresses (e.g. childbirth) up to a 10-fold increase.
- Palliative treatment of malignancies: initially 3-20 mg / day, with longer duration of therapy 4-12 mg / day.
- Treatment of some malignancies (e.g. symptomatic multiple myeloma, acute lymphoblastic leukemia, Hodgkin's disease and non-Hodgkin's lymphoma) in combination with other medicinal products: the usual dose is 40 mg or 20 mg once a day.
- Prevention and treatment of cytotoxic-induced vomiting (chemotherapy): 8-20 mg before chemotherapy, then 4-16 mg if needed for 1-3 days.
- Prophylaxis and treatment of postoperative vomiting: a single dose of 8 mg prior to surgery.

Method of administration
The tablets are for oral use.

Take the tablets during or after a meal. Swallow them whole with enough fluid. If possible, the daily dose should be taken as a single dose in the morning. In diseases requiring high dose treatment, multiple daily dosing is often required to maximize the effect.

Duration of treatment
The duration of treatment depends on the underlying disease and the course of the disease. Your doctor will prescribe a treatment regimen that you must strictly follow. Once a satisfactory treatment outcome has been achieved, the dose will be reduced to a maintenance dose or the treatment will be discontinued. In principle, the dose should be gradually reduced.

With reduced thyroid activity or liver cirrhosis, low doses may be sufficient or a dose reduction may be necessary.

Use in children
If a child is taking this medicine, it is important that the doctor monitors their growth and development at frequent intervals.

If you use more Prednisolon F than you should
Even if taken in large amount for a short time, dexamethasone is usually tolerated without complications. No special measures are required. If you notice any enhanced or abnormal effects, you should talk to your doctor.

If you forget to use Prednisolon F
If you have missed a single dose, take it as soon as you remember. Do not use a double dose to make up for forgotten dose. Take the next dose at the regular time.

If you stop using Prednisolon F
Always follow the dosage regimen prescribed by your doctor. Prednisolone F should never be discontinued without authorization, especially after prolonged treatment, as it may lead to a reduction in glucocorticoid formation in the body (reduced adrenal cortex function).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects

In hormone replacement therapy, the risk of side effects is low at the recommended dose. With prolonged administration, especially at high doses, side effects of various severity may usually be expected but their frequency cannot be clearly determined.

Infections and infestations
Masking of infections, appearance and / or exacerbation of viral infections, fungal infections, bacterial, parasitic and opportunistic infections, activation of parasitic infection (amoebas, worms).

Blood and lymphatic system disorders
Changes in blood count (increased number of white or red blood cells, decreased number of some types of white blood cells, changes in blood clotting).

Immune system disorders
Hypersensitivity reactions (e.g. drug rash), anaphylactic reactions (severe allergic reactions), weakening of the immune system.

Endocrine system disorders
Suppression of the adrenal glands and the occurrence of Cushing's syndrome (typical symptoms include: lunar face, central obesity and thinning and reddening of the skin), secondary adrenal and pituitary insufficiency (especially during stress, e.g. trauma or surgery), growth retardation in children, in childhood and adolescence, menstrual disorders and absence of menstruation, increased hair growth

Metabolism and nutrition disorders
Sodium retention with edema, increased potassium excretion (risk of cardiac arrhythmias), weight gain, decreased glucose tolerance (pre-diabetic status), diabetes mellitus, elevated cholesterol and triglycerides, increased appetite.

Psychiatric disorders
Depression, irritability, euphoria, increased tension, psychoses, obsession, hallucinations, emotional lability, anxiety, sleep disturbance, aggravated schizophrenia, suicidal tendency.

Nervous system disorders
Elevated intracranial pressure, manifestation of epilepsy that has not been shown to date,

increased tendency to develop seizures with already manifested epilepsy, vertigo, headache.

Eye disorders
Lens haze (cataracts / eye curtain), elevation of intraocular pressure (glaucoma), worsening of corneal ulcer symptoms, increased viral, fungal and bacterial inflammation of the eye, worsening of corneal inflammation, pupil enlargement, conjunctival edema, sclera perforation, blurred vision.

Cardiac disorders
Rupture of heart muscle after recent heart attack, congestive heart failure in predisposed people, heart decompensation.

Vascular disorders
High blood pressure, increased risk of atherosclerosis and thrombosis, inflammation of the blood vessels (also withdrawal syndrome after prolonged therapy), increased breakability of capillary vessels.

Gastrointestinal disorders
Stomach discomfort, feeling sick, being sick, gastrointestinal ulcers, gastrointestinal bleeding, acute inflammation of the pancreas, inflammation of ulcer of esophagus, candidiasis of esophagus (thrush).

Thinned delicate skin, unusual marks on the skin, bruising, redness and inflammation of the skin, stretch marks, visible swollen capillaries, acne, increased sweating, skin rash, swelling, thinning of the hair, unusual fat deposits, excessive hair growth, water retaining in the body,

pigment disorders, weakened capillaries that rupture easily, observed as bleeding under the skin (increased capillary fragility), skin irritation around the mouth (perioral dermatitis)

Skin and subcutaneous tissue disorders
Thinned delicate skin, enlarged subcutaneous blood vessels, tendency to bruise / bruising, skin bleeding as dots or spots due to increased capillary fragility, increased hair growth on body, acne, thinning of the hair, pigment disorders, inflammation of the skin of the face especially around the mouth, nose and eyes, changes in the coloring of the skin.

Musculoskeletal and connective tissue disorders
Muscular injuries, muscular weakness and muscle loss, bone loss (osteoporosis) related to the dose and possible even in short-term use; bone disorders (aseptic bone necrosis), tendon disorder and inflammation, tendon rupture, fatty deposits in the spine (epidural lipomatosis), growth inhibition in children (premature epiphyseal closure)

Note:
A too rapid dose reduction after prolonged treatment can cause symptoms such as muscle and joint pain

Reproductive system and breast disorders
Sex hormone secretion disorders (as a consequence: irregular or absent menstruation (amenorrhea), male hair pattern growth in women (hirsutism), impotence).

General disorders and administration site conditions
Impaired reaction to vaccination and skin tests. Slow wound healing. 'Withdrawal syndrome' (fever, muscle and joint pain, rhinitis, weight loss, inflammation of the eye (conjunctivitis), painful itchy skin nodules, weight loss.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 София
T: +359 28903417
website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prednisolon F

Store in the original package at temperatures below 25 °C.

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prednisolon F contains
- The active substance in one tablet is dexamethasone 2 mg
- The other ingredients are lactose monohydrate, maize starch, magnesium stearate

What Prednisolon F looks like and contents of the pack

White or off white, round, flat tablets with a diameter of 6 mm and engraved with "D2" on one side.

10 (ten) tablets are packed in a PVC / PVdC / AL foil blister.

5 (five) blisters per carton box.

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