

## **Prednisolon 5 mg tablets**

### **prednisolone**

#### **What is prednisolon and what is it used for?**

**Drug group:** Prednisolone belongs to the group of adrenal cortex hormones (corticosteroids). These drugs suppress inflammatory reactions and hypersensitivity reactions. In addition, prednisolone has an influence on sugar and protein metabolism.

#### **Uses:**

- certain rheumatic diseases
- certain lung diseases (e.g. COPD)
- certain stomach and intestinal diseases (e.g. ulcerative colitis, Crohn's disease)
- certain forms of liver inflammation
- certain blood disorders
- nephrotic syndrome (kidney disorder)
- congenital adrenal hyperplasia, poorly functioning adrenal gland
- certain types of cancer
- sudden worsening of multiple sclerosis symptoms
- brain edema
- certain eye disorders (e.g. eye inflammation)
- severe skin conditions
- In case of severe hypersensitivity reactions
- In suppressing immune responses in organ transplantations
- In suppressing nausea and vomiting during cancer treatment

#### **When should you not use this medicine or be extra careful with it?**

##### **When should you not use this medicine?**

- If you are allergic to any of the substances in this medicine. You can find these substances in section 6.
- If you have a stomach or intestinal ulcer
- If you have an infection (inflammation) caused by viruses, fungi, or bacteria
- If you have an infection (inflammation) caused by tropical worms
- If you have been vaccinated with a live attenuated virus less than 2 weeks ago (see also "Be extra careful with Prednisolone 5 mg")
- In case of a certain eye infection (herpes simplex infection)
- When should you be extra careful with this medicine?
- If you have had a stomach or intestinal ulcer before; prednisolone can cause a new ulcer
- If you have high blood pressure, bone loss, mental disorders, or tuberculosis (TB); you must follow your doctor's instructions carefully
- If you have diabetes; you must monitor your blood sugar levels more closely because they may become disrupted with the use of prednisolone
- If prednisolone is given to children; growth and physical development should be monitored during long-term administration

Contact your doctor before using this medicine if you have scleroderma (also known as generalized sclerosis, an autoimmune disease), as daily doses of 15 mg or higher of this medicine can increase the risk of a serious complication (called scleroderma renal crisis). Signs of scleroderma renal crisis include high blood pressure and decreased urine production. The doctor may advise you to have your blood pressure and urine checked regularly.

Prednisolone should only be used in principle for a disease with a proven diagnosis and when treatment with simpler medicines is not possible.

Prednisolone can suppress certain symptoms of an infection (inflammation) and new infections may occur during its application. Infections caused by bacteria must be treated before prednisolone is administered. Preferably, you should not be vaccinated during treatment with prednisolone.

If you need to undergo surgery or have a serious injury or accompanying illness during or after treatment with this medicine, you should inform your doctor that you are using or have used prednisolone.

Contact your doctor if you experience blurred vision or other visual disturbances during or after treatment with this medicine.

For long-term therapy, regular eye check-ups are highly recommended. Monitoring of blood sugar levels may also be necessary. The discontinuation of treatment should preferably be done gradually and under strict supervision of your doctor. Contact your doctor or pharmacist before using this medication. Are you currently taking any other medications, or have you recently taken any or plan to take any in the near future? If so, inform your doctor or pharmacist. This also applies to medications that do not require a prescription. Interaction means that drugs can affect each other's effects and/or side effects when used simultaneously. Interaction may occur when using these tablets with:

- phenytoin, phenobarbital (anti-epileptic drugs); prednisolone's effectiveness may decrease
- rifampicin (bactericidal drug); prednisolone's effectiveness may decrease
- diuretics (such as furosemide, bumetanide); there is an increased risk of low potassium in the blood
- anticoagulants (acenocoumarol, phenprocoumon); prednisolone may reduce the effectiveness of anticoagulants

- drugs for diabetes (such as tolbutamide, glibenclamide, gliclazide); blood sugar-lowering effects of diabetes drugs may decrease
- drugs that can also cause stomach or intestinal ulcers as side effects (such as painkillers like acetylsalicylic acid, diclofenac, and ibuprofen)

Some drugs can enhance the effects of Prednisolon 5 mg, and your doctor may want to monitor you carefully if you are taking these drugs (including some HIV drugs: ritonavir, cobicistat).

**Pregnancy and breastfeeding:** If you are pregnant, think you may be pregnant, planning to become pregnant, or breastfeeding, contact your doctor or pharmacist before using this medication. There is insufficient data on the potential harm of prednisolone in humans during pregnancy. Use during pregnancy is only recommended on the explicit advice of a doctor. Prednisolone is excreted in breast milk, so do not use this medication during the period of breastfeeding.

**Driving and using machines:** In some cases, this medication may cause muscle weakness, muscle breakdown, and mood changes. Be careful when performing activities that require alertness, such as driving or operating machinery. Consult your doctor if you have any questions about this. Traffic, operating machinery, and working at heights require caution while taking this medication. Keep a close eye on children who are using this medication while playing on the street.

#### How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

**Dosage:** The dosage depends heavily on the nature and severity of the disease for which your doctor has prescribed prednisolon.

Prednisolon can be given as: a short course of treatment

long-term intensive therapy where the dose is often gradually reduced long-term supportive therapy

If you notice that Prednisolon 5 mg is too strong or not working enough, consult your doctor or pharmacist.

#### Method of use

- The tablets are best taken before or during a meal with a large amount of milk or water (= one glass).
- The break line is there to break the tablet if you have trouble swallowing the whole tablet.

#### Did you use too much of this medicine?

- If you have taken too much Prednisolon 5 mg, contact your doctor or pharmacist immediately.
- There are no known symptoms of prednisolon overdose.

#### Did you forget to use this medicine?

If you missed a dose, take the missed dose as soon as possible. However, if it is almost time for your next dose, skip the missed dose and continue with your normal dosing schedule. Never take a double dose of Prednisolon 5 mg to make up for the missed dose.

**If you stop using this medication:** When you abruptly stop using prednisolone, the symptoms that existed before the start of treatment may reoccur. Complications can also occur more quickly and the hormone control system of the adrenal gland has less opportunity to recover. This mainly applies to long-term therapy. The use should be gradually reduced to give the "lazy" adrenal gland the opportunity to produce hormones again. Always consult your doctor if you are in doubt.

#### Possible side effects

Like any medication, this medication can have side effects, although not everyone experiences them.

**The following side effects may occur, among others: Immune system:** Reduced resistance which increases the risk of infections, unfavorable course of infections, reactivation of non-visible tuberculosis (infection disease characterized by nodules on the tissue) and infections caused by parasites. Making the warning signals for tissue death (sepsis) and breaking of organ walls (perforation) less recognizable. Hypersensitivity reactions (excessive reaction to stimuli from the environment). These hypersensitivity reactions can be very severe and can manifest themselves through the following symptoms: itching, burning sensation of the tongue and throat, short and rapid pulse, excessive sweating, shortness of breath immediately followed by (very) severe shortness of breath and shock (sharp drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin, decreased consciousness) due to a sudden strong dilation of blood vessels as a result of severe hypersensitivity to certain substances (anaphylactic shock), often preceded by or accompanied by characteristic skin abnormalities.

**Blood vessels: Risk of high blood pressure.:** The following abnormalities may be found in blood tests: An increase in the number of red blood cells (erythrocytosis), an increase in the number of white blood cells in the blood (granulocytosis), a decrease in the amount of certain white blood cells (lymphopenia), a decrease in the amount of red blood cells (eosinopenia).

**Hormone system:** Growth retardation in children, disturbed menstrual pattern, insufficient adrenal cortex function when exposed to stress (trauma, surgery, infection), obesity, characterized by a full moon face. (Cushing's syndrome), decreased carbohydrate tolerance. The latter can reveal an underlying

slumbering diabetes. The first symptoms of this are a feeling of thirst, frequent urination and weight loss. If you are already using blood sugar-lowering medication, an increase in dosage may be necessary.

**Nervous system:** Increased pressure in the skull with accumulation of fluid in the eyes, especially in children during or shortly after rapid discontinuation of therapy, mood changes such as happiness, anxiety or depression, insomnia, severe mental illness in which control over one's own behavior and actions is disturbed (psychose).

**Eyes:** Cataracts, green cataracts, increased eye pressure, accumulation of fluid in the retina (central serous chorioretinopathy), blurry vision.

**Heart:** Heart failure in patients who have a certain predisposition.

Slow heart rate (frequency unknown: cannot be determined with available data).

**Stomach and intestines:** Stomach and intestinal disorders with a risk of stomach/intestinal ulcers with bleeding and tears (perforation), inflammation of the esophagus, inflammation of the pancreas.

**Skin:** Skin atrophy, with a high risk of subcutaneous bleeding, dilation of blood vessels in the face (flushing), acne, excessive hair growth, stretch marks, impaired wound healing, suppressed skin reaction in skin tests, hypersensitivity reactions, such as rash with severe itching and formation of bumps (hives or urticaria).

**Bones and muscles:** Muscle weakness and muscle atrophy, bone loss with a risk of vertebral fractures, bone necrosis, especially in the head of the femur.

**Urinary tract and kidneys:** Scleroderma renal crisis in patients who already have scleroderma (an autoimmune disease). Signs of scleroderma renal crisis include high blood pressure and decreased urine production.

**Other:** Breakdown of proteins causing an imbalance of nitrogen in the body, disturbance of fluid and salt balance, accumulation of fluid, increased appetite, to be limited by dietary measures, a risk of potassium deficiency which is mainly characterized by muscle weakness, fatigue and an irregular heartbeat.

**How to store this medicine?**

Store below 25°C