
Package leaflet: Information for the patient**Prednisolone TD 20 mg tablets**

active substance: prednisolone

- **Prednisolone TD 20 mg is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Prednisolone TD 20 mg can cause side effects in some people** (read section 4 below). Some problems such as mood changes (feeling depressed, or “high”), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, but see your doctor straight away.
- **Some side effects only happen after weeks or months.** These include weakness of arms and legs, or developing a rounder face (read section 4 for more information).
- **If you take it for more than 3 weeks, you will get a “steroid card”:** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, see your doctor straight away.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

Read all of this leaflet carefully before you start taking 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

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- 2. What you need to know before you take Prednisolone TD 20 mg**
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1. What Prednisolone TD 20 mg is and what it is used for

Prednisolone TD 20 mg belongs to a group of medicines called steroids. Their full name is corticosteroids.

These corticosteroids occur naturally in the body, and help to maintain health and well-being.

Boosting your body with extra corticosteroid (such as Prednisolone TD 20 mg) is an effective way to treat various illnesses involving inflammation in the body.

Prednisolone TD 20 mg is used to treat inflammatory and allergic disorders, including rheumatoid arthritis, asthma, myasthenia gravis (serious weakness of muscles), allergic skin reactions, collagen disease or inflammatory diseases of the bowel.

Prednisolone TD 20 mg reduces this inflammation, which could otherwise go on making your condition worse.

2. What you need to know before you take Prednisolone TD 20 mg

Do not take Prednisolone TD 20 mg:

- if you are **allergic** to prednisolone or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- if you have **cold sores** that affect the eyes;
- if you have an **untreated infection**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolone TD 20 mg if you

- have been in contact with anyone who has chicken pox, shingles or measles. Contact your doctor immediately for advice.
- have a family history of diabetes or glaucoma.
- are pregnant, plan to become pregnant, or are breast-feeding.
- have osteoporosis, high blood pressure, a recent heart attack, a stomach ulcer, an underactive thyroid gland, epilepsy, tuberculosis or septicaemia.
- have taken Prednisolone TD 20 mg (or a similar medicine) before and had muscular problems (steroid myopathy).
- have heart, kidney or liver problems/disease.
- suffer or have suffered from any mental illness.
- are being treated with vaccines.
- have ever had severe depression or manic-depression (bipolar disorder). This includes having/had depression before/while taking steroid medicines like Prednisolone TD 20 mg or any of your close family has/had these illnesses.
- mental problems while taking Prednisolone TD 20 mg:
Mental health problems can happen while taking steroids like Prednisolone TD 20 mg (see also section 4. "Possible side effects").
 - These illnesses can be serious.
 - Usually they start within a few days or weeks of starting the medicine.
 - They are more likely to happen at high doses.
 - Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Children and adolescents

Prednisolone TD 20 mg should not be applied in children and adolescents because of the risk of growth inhibition. If there are compelling medical reasons for an application, the growth in length should be checked regularly.

Other medicines and Prednisolone TD 20 mg

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription. The following medicines may interact with Prednisolone TD 20 mg:

- Medicines to treat high blood pressure or diuretics ("de-watering tablets").

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- Medicines to treat epilepsy such as carbamazepine, phenobarbital, other barbiturates, phenytoin, primidone, phenylbutazone.
 - Medicines for diabetes including insulin.
 - Medicines to treat infections such as rifabutin, rifampicin, amphotericin, ketoconazole, tetracycline.
 - Medicines used to treat cancer such as etoposide.
 - Methotrexate (for arthritis, Crohn's disease, psoriasis).
 - Mifepristone (used for abortion).
 - Ciclosporin (to prevent organ transplant rejection).
 - Anticoagulant drugs used to thin blood.
 - Oral contraceptives (the "pill").
 - Other non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin.
 - Aminoglutethimide, acetazolamide, carboxolone or salicylates.
 - Retinoids (for skin conditions).
 - Antacids (for indigestion).
 - Carbimazole (for hyperthyroidism).
 - Theophylline (for asthma).

Pregnancy and breast-feeding

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

During pregnancy, you should take this medicine only on the advice of your doctor. So tell your doctor if you are already pregnant or become pregnant. Growth disorders in the unborn child cannot be ruled out if long-term treatment with prednisolone is given during pregnancy. If Prednisolone TD 20 mg is taken at the end of pregnancy, atrophy (shrinkage) of the adrenal cortex may occur in the newborn infant.

Prednisolone is excreted in human milk. No cases of damage have been reported in breast-fed infants to date. Nevertheless, the need to administer Prednisolone TD 20 mg during breast-feeding should be assessed with extreme care. If relatively high doses are required due to your illness, you should stop breast-feeding.

Driving and using machines

If you do not have enough sleep you may be less alert and patients should make sure they are not affected before driving or operating machinery.

Prednisolone TD 20 mg contains lactose

This medicine contains lactose. Therefore please take Prednisolone TD 20 mg only after consultation with your doctor if you are aware that you have intolerance to some sugars.

3. How to take Prednisolone TD 20 mg

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You will be supplied with a "Steroid Treatment Card" which includes important details of your treatment. This card should be carried at all times.

The tablet can be divided into equal doses. The dose will be set by your doctor. Please adhere to the dosing instructions as Prednisolone TD 20 mg may otherwise has not the desired effect.

Take the tablets unchewed during or directly after a meal with a glass of water..

The recommended dose is:

Adults: The usual starting dose is 20-40 mg daily. In severe cases the dosage may be increased up to 60 mg but will be reduced to a maintenance dose of 5-20 mg daily to control your condition once a favorable response is noted.

Children do not take as many tablets as adults. Your doctor will suggest the correct number of tablets for them to take.

For lower doses tablets of other strengths or other forms of prednisolone are recommended.

Once a dose is established, it may be changed to use the lowest effective dose depending on your response to the drug.

If you are diabetic, you may find that you need to take more medication to balance the effect of Prednisolone TD 20 mg. You should discuss this with your doctor.

Your doctor should check your progress at regular visits. Also, your progress may have to be checked after you have stopped using this medicine, since some of the effects may continue.

If you take more Prednisolone TD 20 mg than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any tablets contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Prednisolone TD 20 mg

If you forget to take a dose at the right time, take one as soon as you remember and then your next dose at the usual time. **Never** take two doses at the same time.

If you stop taking Prednisolone TD 20 mg

If you stop taking the tablets suddenly you may develop muscle or joint pain, conjunctivitis, fever, weight loss, painful itchy skin lumps or runny nose.

If you have any further questions on 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.

Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

Stop taking Prednisolone TD 20 mg and contact your doctor straight away if the following allergic reaction happens: puffy, swollen face, tongue or body, which may cause shortness of breath, shock and collapse.

Tell your doctor straight away if the following happens:

- Inflammation of the pancreas (very severe abdominal pains).
- Steroids including Prednisolone TD 20 mg can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Prednisolone TD 20 mg:
 - Feeling depressed, including thinking about suicide.
 - Feeling high (mania) or moods that go up and down.
 - Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.

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- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.
 - Feeling dependant or addicted to this product.

Tell your doctor if the following occurs:

Infections and infestations: lowered resistance to infections, such as a cold, existing eye infections may become worse or symptoms of a previous infection such as tuberculosis (TB) may happen more easily. This is especially important regarding chicken pox or measles.

Gastrointestinal disorders: increased appetite, indigestion, a feeling of being full or bloated, very sore throat and white areas inside your mouth (oral thrush), feeling sick, weight gain, stomach ulcers or perforation (you may feel sick, have pain after eating), particularly in those with Irritable Bowel Syndrome (IBS).

Cardiac disorders: high blood pressure, congestive heart failure in those already at risk.

Nervous system disorders: unusual tiredness or weakness, nervousness, euphoria, depression, insomnia, worsening of schizophrenia, increased pressure in the skull (causing painful eyes, changes in vision or a bad headache, especially behind your eyes), irritability, changes in behaviour.

Skin and subcutaneous tissue disorders: reddish purple lines, thin skin, unusual bruising, acne, wounds that will not heal.

Musculoskeletal and connective tissue disorders: muscle weakness or wasting, pain in back, hips, ribs, arms, shoulders or legs, osteoporosis (may be easier to fracture your bones or to tear your tendons).

Endocrine disorders: filling or rounding out of the face, periods become irregular or stop altogether, unusual increase in hair growth on body or face, changes in blood glucose levels (diabetics may need a change of dose in antidiabetic treatment), changes in protein and calcium in the body, weight gain. Growth in infancy, childhood and adolescence may be reduced.

Renal and urinary disorders: urinating at night, water and salt retention, loss of potassium in the urine.

Blood and lymphatic system disorders: blood clots, dilation of blood vessels, changes in the balance of minerals in the blood (detected by a blood test).

Eye disorders: cataracts, increased pressure in the eye (glaucoma), thinning of the tissues of the eye, pressure on the nerve of the eye, changes in vision, seeing “floaters”, or eye pain.

General disorders: allergic reactions, hiccup, worsening of epilepsy, generally feeling unwell.

Withdrawal symptoms: muscle or joint pain, conjunctivitis, fever, weight loss, runny nose and painful, itchy skin lumps.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte [*Federal Institute for Drugs and Medical Devices*], Abt. Pharmakovigilanz [*Pharmacovigilance Department*], Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, Germany, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prednisolone TD 20 mg

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

Do not store above 25 °C. Keep the blisters in the outer carton in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton and blister 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 Prednisolone TD 20 mg contains**

The active substance is prednisolone.

1 tablet contains 20 mg of prednisolone.

The other ingredients are: lactose monohydrate, maize starch, povidone, purified talc, colloidal anhydrous silica, magnesium stearate.

What Prednisolone TD 20 mg looks like and contents of the pack

White, round, biconvex tablet with a cross-scoreline on one side.

Prednisolone TD 20 mg is available in packs with 20 tablets.

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Made in Germany.

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