

**Uncommon** (may affect up to 1 in 100 people):

- Mental disorders (at high doses)
- Cataracts, glaucoma.

**Rare** (may affect up to 1 in 1,000 people):

- Depression
- Mania in patients without a history of psychiatric illness
- Benign pressure increase in the skull
- Breakdown of bone tissue, tendon rupture.

**Not known** (frequency cannot be estimated from the available data):

- Increased number of white blood cells (leukocytosis)
- Withdrawal syndrome when reducing the dose (see section 3)
- Lowered blood pH, decreased blood potassium, elevated blood fats, impaired sugar tolerance, accumulation of fatty tissue at secluded places in the body, increased appetite (which can lead to weight gain)
- Emotional symptoms (such as elation, emotional instability, drug dependence), mental disorder (such as delusions, hallucinations and schizophrenia), personality change, confusion, anxiety, mood swings, abnormal behaviour, sleep problems, irritability
- Seizures, problems with memory, intellectual disturbance, dizziness, headache, increased amount of fat around the spinal cord
- Acid reduction (central serous chorioretinopathy), protruding eyes, blurred vision
- Heart failure (in susceptible patients)
- Slow heart rate
- Blood clots
- Hiccups
- Gastric ulcer, hole (perforation) in the gut, inflammation of the pancreas, inflammation and ulcers of the oesophagus, swollen abdomen, abdominal pain, diarrhoea, digestive problems, nausea
- Increased hairiness in women, bleeding of the skin, bruising, redness of the skin, sweating, stretch marks (blue-red patches on the chest and abdomen), itching, hives, acne
- Muscle weakness, muscle aches, bone fractures without prior trauma, joint breakdown, joint pain
- Irregular menstrual periods
- Tiredness, feeling ill
- Increased amount of calcium in the urine, elevated liver enzymes (alanine aminotransferase, aspartate aminotransferase), elevated alkaline phosphatase in the blood, elevated levels of blood urea (seen in blood tests), weaker reaction to skin tests.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

#### 5. How to store Prednisolone Tablets

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

Do not take this medicine after the expiry date which is stated on the carton or the foil blister strip. The expiry date refers to the last day of that month.

2.5mg; 5mg tablets

Do not store above 25°C.

Keep the blister packs in the outer carton in order to protect from light.

10mg; 20mg; 25mg; 30mg tablets

Keep the blister packs in the outer carton in order to protect from light.

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 Tablets contain

**The active substance is prednisolone.** Each tablet contains either 2.5mg, 5mg, 10mg, 20mg, 25mg or 30mg of the active ingredient.

The tablet also contains lactose monohydrate, pregelatinised starch, sodium starch glycolate (type A), iron oxide yellow (E172), iron oxide red (E172), glycerol dibehenate, magnesium stearate.

##### What Prednisolone Tablets look like and contents of the pack

2.5mg tablet

Yellow, 7mm, round, flat, tablet, with a score line on one side, imprinted with "A610" on one side and "2.5" on the other.

5mg tablet

White, 7mm, round, flat, tablet, with a score line on one side, imprinted with "A620" on one side and "5" on the other.

10mg tablet

Red, 7mm, round, flat, tablet, with a score line on one side, imprinted with "A630" on one side and "10" on the other.

20mg tablet

Red, 9mm, round, flat, tablet, with a score line on one side, imprinted with "A640" on one side and "20" on the other.

25mg tablet

White, 9mm, round, flat, tablet, with a score line on one side, imprinted with "A650" on one side and "25" on the other.

30mg tablet

Yellow, 9mm, round, flat, tablet, with a score line on one side, imprinted with "A670" on one side and "30" on the other.

They are available in packs of 28 tablets. The 25mg tablet is also available in packs of 56 tablets.

##### Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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Package leaflet: Information for the patient

## Prednisolone 2.5mg, 5mg, 10mg, 20mg, 25mg and 30mg Tablets

- **Prednisolone 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 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 blue 'steroid card':** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chickenpox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away.

#### 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

1. What Prednisolone Tablets are and what they are used for
2. What you need to know before you take Prednisolone Tablets
3. How to take Prednisolone Tablets
4. Possible side effects
5. How to store Prednisolone Tablets
6. Contents of the pack and other information

#### 1. What Prednisolone Tablets are and what they are used for

Prednisolone Tablets belong 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 corticosteroids (such as Prednisolone Tablets) is an effective way to treat various illnesses involving inflammation in the body. Prednisolone Tablets reduce this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Prednisolone Tablets are used in a wide range of inflammatory and auto-immune conditions including:

- allergies, including severe allergic reactions
- inflammation affecting the:
  - lungs, including asthma
  - blood vessels and heart
  - bowel or kidneys
  - muscles and joints, including rheumatoid arthritis
  - eye or nervous system
- skin conditions
- some infections
- some cancers, including leukaemia, lymphoma and myeloma
- to prevent organ rejection after a transplant.

Also:

- to boost steroid levels when the body is not making enough natural steroid on its own
- to treat high calcium levels.

#### 2. What you need to know before you take Prednisolone Tablets

**Do not take Prednisolone Tablets** if you:

- are **allergic** to prednisolone or any of the other ingredients of this medicine (listed in section 6).
- have a **fungal infection**
- have recently had any **'live' vaccinations**.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolone Tablets if you have:

- an infection or get an infection while being treated with prednisolone
- underactive thyroid gland (hypothyroidism)
- liver disease or kidney failure
- or have had seizures
- myasthenia gravis (a disease that causes muscle weakness)
- tuberculosis or have ever been treated for tuberculosis
- gastric ulcer, duodenal ulcer or inflammatory bowel disease (e.g. ulcerative colitis or diverticulitis)
- diabetes
- heart disease, e.g. heart failure or high blood pressure

- had blood clots in the past (e.g. vein thrombosis) or have blood clots
- mood swings or psychotic tendencies
- any drug allergy
- osteoporosis
- adrenal tumour (phaeochromocytoma)
- new surgically created blood vessels or intestinal connections
- scleroderma (also called systemic sclerosis, an autoimmune disease) as daily doses of 15mg or more can increase the risk of a serious complication called acute kidney crisis. Signs of acute kidney crisis include high blood pressure and decreased urine output. Your doctor may advise you to check your blood pressure and urine levels regularly.

**Contact your doctor** if during treatment you:

- get serious psychological side effects, e.g. depression and suicidal thoughts. These can also occur when you stop taking prednisolone.
- experience blurred vision or other visual disturbances.
- are subjected to unusually severe physical or mental strain of any kind (e.g. infection, surgery, trauma) while you are being treated with prednisolone. The dose may need to be increased.

#### Increased susceptibility to infections

Prednisolone treatment can reduce your resistance to infections, making it easier for you to contract infections during treatment. Chickenpox and measles can become more serious when taking cortisone preparations. Therefore, if you have not previously had these diseases, you should avoid exposing yourself to chickenpox or measles during treatment and talk to a doctor straight away if this should still happen.

- You are more likely to develop **infections** whilst taking Prednisolone Tablets, and existing infections may become worse, especially during periods of stress. Certain infections can be serious if not controlled.
- You may become very ill if you get chickenpox whilst taking Prednisolone Tablets. You should avoid contact with people who have **chickenpox or shingles** whilst taking, and for up to 3 months after you have stopped taking, Prednisolone Tablets. Do not stop taking Prednisolone Tablets.
- You should avoid contact with people who have **measles**.

If you need to be vaccinated during prednisolone treatment, tell your doctor about your treatment before you receive the vaccination.

Tumour lysis syndrome can occur when corticosteroids are used in cancer treatment. Tell your doctor if you have cancer and have symptoms of tumour lysis syndrome such as muscle cramps, muscle weakness, confusion, irregular heartbeat, vision loss or disturbances, and shortness of breath.

Corticosteroids can cause growth retardation in infants, children and adolescents and therefore long-term use should be avoided. If long-term use is necessary, the growth of infants and children will be closely monitored by the physician.

#### Other medicines and Prednisolone Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. It is especially important to tell your doctor if you are taking any of the following medicines:

- rifampicin, isoniazid (to treat tuberculosis)
- blood thinners
- carbamazepine, phenobarbital, phenytoin (anti-epilepsy drug)
- anticholinergics (e.g. medicines for Parkinson's disease or asthma)
- cholinesterase inhibitors (for myasthenia gravis or Alzheimer's disease)
- insulin or diabetes drugs in the form of tablets. Cortisone preparations can impair the blood sugar lowering effect of diabetes drugs
- cobicistat (for HIV infection)
- oestrogens (e.g. birth control pills)
- acetylsalicylic acid or other non-steroidal anti-inflammatory agents (NSAIDs) (used to treat pain and inflammation). The risk of peptic ulcer may increase when combined with cortisone preparations
- thiazides, furosemide, ethacrynic acid (potassium-lowering diuretics)
- xanthines (e.g. theophylline, for treating asthma)
- beta-2 stimulants (e.g. salbutamol, terbutaline, salmeterol, formoterol, for treating asthma)
- amphotericin B (antibiotic for fungal infection).

If you need to be vaccinated, tell your doctor that you are taking Prednisolone Tablets.

#### Pregnancy and breast-feeding

##### Pregnancy

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

##### Breast-feeding

If you are breast-feeding, you must tell your doctor before you start the treatment. Your doctor will want to examine your baby during your time of treatment. Small amounts of steroids are present in breast milk.

##### Driving and using machines

Dizziness, visual disturbances and fatigue can occur when using prednisolone. If you experience such symptoms, do not drive or use machines. You are responsible for assessing whether you are in a position to drive a motor vehicle or perform work that requires increased attention. One of the factors that may affect your ability in these respects is the use of drugs because of their effects and / or side effects. A description of these effects and side effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are unsure.

##### Prednisolone Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact them before taking this medicine.

##### Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### 3. How to take Prednisolone Tablets

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

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

Prednisolone tablets should be taken following a meal to reduce the risk of gastric irritation.

Different illnesses require different doses of Prednisolone Tablets. Depending on your illness your daily dose may be between 5 and 60mg. In some cases you may be instructed to take it every other day. Your doctor will decide when and how to treat you with Prednisolone Tablets.

Once your condition starts to get better, your doctor may change your dosage to a lower one. Your doctor may also reduce your dosage before stopping treatment completely. This may depend on your illness, your dosage and how long you have been taking this medicine. In all cases you should be careful to follow any changes.

#### Treatment of the elderly

When steroids are taken by elderly patients some of the unwanted side effects can be more serious especially brittle bone disease, diabetes, high blood pressure, infections and thinning of the skin.

Whilst you are taking Prednisolone Tablets, if you develop chickenpox, shingles, measles or any infection tell your doctor straight away (refer to section 2 'Increased susceptibility to infections').

Your doctor will give you a Steroid Treatment Card. You must carry it with you at all times. You should show your Steroid Treatment Card to anyone who is giving you treatment such as a doctor, nurse or dentist.

#### Mental problems while taking Prednisolone Tablets

Mental health problems can happen while taking steroids like Prednisolone Tablets (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 occur, 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 occurred when doses are being lowered or stopped.

#### Use in children and adolescents

The use of steroids can slow down normal growth of children and adolescents. In order to lessen this effect the tablets are often taken in a single dose every other day.

#### If you take more Prednisolone Tablets 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, contact your nearest hospital casualty department or tell your doctor immediately. Show any leftover medicines or the empty packet to the doctor.

#### If you forget to take Prednisolone Tablets

If you forget to take a dose, take one as soon as you remember and then your next dose at the usual time. **Never** take a double dose to make up for a forgotten dose.

#### If you stop taking Prednisolone Tablets

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. In some severe cases a drop in blood pressure and death may occur. If you have been given Prednisolone Tablets for more than 3 weeks your doctor will ensure that your dose is gradually reduced so as to avoid any withdrawal symptoms. It is important that you complete the course of treatment as per your doctor's instructions.

**Talk to your doctor before** you stop taking the tablets and follow their advice.

**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.

Side effects mainly occur with long-term treatment, but also depend on dose size and individual sensitivity.

**Contact your doctor immediately** if the following serious side effects occur:

**Not known** (frequency cannot be estimated from the available data):

- Severe allergic reaction including angioedema. Symptoms may include: swelling of the face, tongue or throat, difficulty swallowing, hives and difficulty breathing, fever, drop in blood pressure.
- Pheochromocytoma crisis, symptoms may include: anxiety, headache, palpitations, sweating, pale skin.
- Acute renal crisis (in patients already suffering from scleroderma, an autoimmune disease, see section 2 'Warnings and precautions'). Symptoms may include: high blood pressure and decreased urine output.
- Suicidal ideation (see section 2 'Warnings and precautions').

#### Other Side effects:

**Common** (may affect up to 1 in 10 people):

- Infections, the immunosuppressive effect of prednisolone may also cause infections to flare up again (e.g. tuberculosis)
- Lower concentration of certain hormones, cushings-like appearance, growth retardation in children
- Low levels of potassium, build-up of sodium in the body, increased sugar in the blood and urine, osteoporosis
- Swelling due to fluid accumulation, high blood pressure
- Thinner skin, impaired wound healing
- Muscle wasting.