

Stomach and intestines – 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.

Heart – high blood pressure.

Nervous system – unusual tiredness or weakness, nervousness, worsening of schizophrenia, increased pressure in the skull (causing painful eyes, changes in vision or a bad headache, especially behind your eyes).

Skin – reddish purple lines, thin skin, unusual bruising, acne, wounds that will not heal.

Muscle or bones – 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).

Hormones – filling or rounding out of the face, periods become irregular or stop altogether, unusual increase in hair growth on body or face. Growth in infancy, childhood and adolescence may be reduced.

Kidney – urinating at night, water and salt retention.

Scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production (not known: frequency cannot be estimated from the available data).

Blood – blood clots, changes in the balance of minerals in the blood (detected by a blood test).

Eyes – cataracts, increased pressure in the eye (glaucoma), thinning of the tissues of the eye, pressure on the nerve of the eye, central serous chorioretinopathy (causing blind spots, distortion of straight lines and objects appearing smaller/further away), blurred vision (not known: frequency cannot be estimated from the available data).

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, 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 at: 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 out of the sight and reach of children. Store in a cool dry place.

Do not use this medicine after the expiry date stated on the label, carton or bottle. The expiry date refers to the last day of that month.

Do not throw away any medicine 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 (the ingredient that makes the tablets work) is prednisolone. Each tablet contains either 2.5mg or 5mg of the active ingredient.
- The tablet also contains lactose, maize starch, microcrystalline cellulose and magnesium stearate.
- The tablet coating contains colloidal silicon dioxide, hydroxypropylmethylcellulose (E464), indigo carmine (E132 – 5mg tablets only), iron oxide (E172 – 2.5mg tablets only), macrogol, polyvinyl acetate phthalate, ponceau 4R (E124 – 5mg tablets only), poly (vinyl alcohol), sodium alginate (E401), sodium hydrogen carbonate (E500), stearic acid, sunset yellow (E110 – 5mg tablets only), talc, titanium dioxide (E171), triethyl citrate (E1505).

What Prednisolone tablets look like and contents of the pack

Prednisolone 5mg are circular, red, gastro-resistant tablets and the 2.5mg tablets are circular, dark brown, gastro-resistant tablets. Pack sizes are 28, 30 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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Package leaflet; Information for the patient

Prednisolone 2.5mg and 5mg Gastro-resistant 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 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**.
 - The full name of this medicine is Prednisolone 2.5mg and 5mg Gastro-resistant Tablets but within the leaflet it will be referred to as Prednisolone tablets.
- 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

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

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). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue. Certain ingredients can cause allergic reactions such as Ponceau 4R and sunset yellow (azo dyes) which can cause asthma (5mg tablets only)
 - have **cold sores** that affect the eyes
 - have an **untreated infection**.

Warnings and precautions

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

- have been in contact with anyone who has **chickenpox, shingles** or **measles**. Contact your doctor immediately for advice
 - have or have a family history of **diabetes** or **glaucoma**
 - have **systemic sclerosis**
 - have **brittle bones, high blood pressure**, a recent **heart attack**, a **stomach ulcer**, an **underactive thyroid gland** or **tuberculosis**
 - have taken prednisolone tablets (or a similar medicine) before and had muscular problems (**steroid myopathy**)
 - have **heart, kidney** or **liver** 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 tablets **or any of your close family** has had these illnesses
 - 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.
- **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 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.

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

Other medicines and Prednisolone tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- antacids – do not take at the same time as the Prednisolone tablets
- diuretics ('water tablets')
- medicines to treat epilepsy such as carbamazepine, phenobarbital, phenytoin, primidone
- medicines for diabetes including insulin
- medicines to treat infections such as rifabutin, rifampicin, amphotericin, ketoconazole, tetracyclines
- medicines used to treat cancer such as methotrexate, etoposide
- anticoagulant drugs used to thin blood
- oral contraceptives (the 'pill')
- other non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin
- mifepristone (used for abortion), ciclosporin, acetazolamide, beta-2-agonists, theophylline, carbenoxolone, aminoglutethimide or carbimazole
- some medicines may increase the effects of Prednisolone tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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.

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.

Prednisolone tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as it contains lactose.

If you see another doctor or go into hospital, let them know what medicines you are taking.

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, especially

if you are elderly. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets **whole, with a little water as a single dose** in the morning after breakfast unless otherwise directed by the doctor. **Do not chew or cut** the tablets.

The recommended dose is

General conditions	5-60mg daily
Allergic and skin disorders	5-15mg daily
Blood disorders	15-60mg daily
Collagenosis	20-30mg daily
Rheumatoid arthritis	10-15mg daily

Elderly

Doses will be decided for the elderly.

Use in children and adolescents

Doses will be decided for children aged 1-17 years.

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

Differences in absorption of prednisolone may be experienced by individuals especially when switching between coated and non-coated prednisolone tablets, therefore close monitoring of your condition is recommended. Talk to your doctor if you notice worsening of your condition or if you have any concerns about your treatment.

If you are diabetic, you may find that you need to take more medication to balance the effect of Prednisolone tablets. 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 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. **Do not** take a double dose to make up for a forgotten dose.

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.

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. **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, particularly when you first start taking it 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 tablets 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 tablets 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 tablets:
 - 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
 - feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Infections - 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 chickenpox or measles.

Endocrine

Cushing's Disease is a hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating.