

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

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

- tiredness, increased number of white blood cells, blood clotting
- heart problems which can cause shortness of breath, high blood pressure (hypertension)
- convulsions, dizziness, vertigo, headache, raised pressure in the brain (which can cause headaches, nausea and vomiting), sleeplessness
- thinning of the skin, bruising, stretch marks, patches of skin reddening, itching, rash, hives, acne, extra hair growth, slow healing of wounds, increased sweating, hiding or altering reactions to skin tests such as for tuberculosis
- reduction of growth in babies, children and adolescents
- absence or irregularity of menstrual periods
- face becomes very round, weight gain
- increased blood sugar, carbohydrate imbalance in diabetes
- euphoria (feeling high), feeling of dependency on treatment, depression, worsening of schizophrenia
- general unwell feeling
- 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
- worsening of epilepsy
- risk of stroke is increased in Horton disease
- vision problems, increased pressure in the eyeball (glaucoma), whitening or clouding of the lens (cataracts), pressure on the nerve to the eye, thinning of the tissues of the eye (sclera and cornea), bulging eyes, worsening of viral or fungal infections of the eye
- risk of contracting infection is increased, existing infections can worsen, signs of infection can be masked, previous infections, such as tuberculosis (TB) may be re-activated (flare up)
- muscle wasting of the upper arms and legs, muscle pain, tendon rupture
- brittle bone disease or wasting of the bones, bone fractures
- indigestion, stomach ulcers with bleeding or perforation, bloating, ulcers in the gullet (oesophagus) which may cause discomfort on swallowing, candidiasis (thrush), abdominal (stomach) pain, increased appetite which may result in weight gain, diarrhoea, water and salt retention, nausea and vomiting
- a change in the levels of some hormones, mineral balance or protein in blood tests
- increased cholesterol or fat levels in blood.

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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accord

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:

- suffer from or have ever been treated for tuberculosis (TB)
- have high blood pressure
- have a heart condition
- have liver or kidney problems
- suffer from diabetes or diabetes runs in your family
- have osteoporosis (thinning of the bone), particularly if you are past the menopause (the change of life).
- are going through, or are past the menopause
- suffer from epilepsy (fits)
- suffer from stomach ulcers
- have taken prednisolone (or other steroids) before and had muscular problems (steroid myopathy)
- are receiving treatment for a condition called myasthenia gravis (a rare muscle weakness disorder)
- have ever had blood clots, (for example, deep vein thrombosis [DVT], or, thromboembolism)
- are planning to have a vaccination.
- have Cushing's disease. (A hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating). suffer from hypothyroidism (an underactive thyroid gland which can cause tiredness or weight gain)
- have Duchenne's muscular dystrophy
- have inflammatory bowel disease such as Crohn's disease
- have an eye disease caused by fluid build-up at the back of the eye that causes visual impairment
- are undergoing immunosuppression therapy for example in the treatment of cancer
- have scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15mg 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.

Children and adolescents

The use of steroids can slow down normal growth of children and adolescents. Your doctor may need to stop treatment or adjust the dose for your child accordingly. If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take prednisolone.

Other medicines and Prednisolone tablets

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

- antivirals such as ritonavir which can be used to treat HIV infection
- antifungals such as ketoconazole and amphotericin which are used to treat fungal infections
- antibiotics such as erythromycin and rifamycin which are used to treat bacterial infections
- antiepileptic drugs such as carbamazepine, phenobarbital, phenytoin and primidone which are used to treat epilepsy
- oestrogens, for example in the contraceptive pill or HRT
- thiazide diuretics ("water tablets") for example bendroflumethiazide used for water retention or high blood pressure
- medicines to treat high blood pressure
- anticoagulants for example warfarin which is used to thin the blood
- carbenoxolone which is used for ulcers
- salbutamol, formoterol, bambuterol, fenoterol, ritodrine, salmeterol and terbutaline used to treat asthma
- antimuscarinics/ anticholinergics
- immunosuppressants which dampen down the activity of the body's immune system
- antacids such as magnesium trisilicate or aluminium hydroxide, used to treat the symptoms of heartburn and indigestion
- drugs for diabetes including insulin
- ciclosporin which is used to treat rheumatic disease, skin complaints or after a transplant
- cardiac glycosides for example digoxin which is used to help strengthen a weak heart
- non-steroidal anti-inflammatory drugs (NSAIDs) for example aspirin, ibuprofen and indometacin used for pain relief or to treat rheumatic disease mifepristone, used to induce labour or abortion
- cytotoxic drugs for example methotrexate which is used to treat cancer
- vaccinations: You must tell your doctor or nurse that you are taking a steroid before you are given any vaccinations. Steroids affect your immune response and you must not be given any live vaccines
- somatropin which is a growth hormone
- acetazolamide which is used in the treatment of glaucoma and epilepsy
- loop diuretics for example furosemide which is used to treat heart failure
- theophylline which is used for asthma and chronic obstructive pulmonary disease (COPD)
- antithyroids such as carbimazole
- isoniazid which is used to treat tuberculosis.

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.

This medicine contains less than 1mmol sodium (23mg) 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, especially if you are elderly. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets **whole, with a little water**. **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)
- painful skin ulcers.

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.