

**Tell your doctor straight away** if you experience any of the following:

- 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. These side effects include:

- 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 (hallucinations). 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 you experience any of the following side effects which have been reported with frequency **Not known** (cannot be estimated from the available data):

**Heart** – high blood pressure, congestive heart failure in those already at risk.

**Stomach and intestines** – increased appetite, indigestion, diarrhoea, feeling sick, feeling bloated, weight gain, stomach ulcers or perforation of the small intestine (you may feel sick, have pain after eating), particularly in those with Irritable Bowel Syndrome (IBS).

**Muscles or bones** – brittle bones (osteoporosis), muscle weakness, and pain, muscle wasting and loss.

**Nervous system** – dizziness, spinning sensation, headache, difficulty in sleeping, worsening of epilepsy, raised pressure in the skull (causing pain behind the eyes).

**Skin** – difficult healing of wounds, unusual increase in hair growth on body or face, skin rashes, unusual bruising, thinning of the skin, acne, appearance of reddish purple lines.

**Hormones** – filling or rounding of the face (Cushing's syndrome), periods become irregular or stop completely, changes in blood glucose levels, weight gain, reduced growth in infancy, childhood and adolescence.

**Kidney** – Frequent urination at night, water and salt retention, loss of potassium in the urine. 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.

**Blood** – blood clots, increase in the number of white blood cells.

**Eyes** – increase pressure in the eye, cataracts, thinning of the tissue of the eye, perforation of the white of the eye, bulging of the eye, blurred vision, central serous chorioretinopathy (causing blind spots, distortion of straight lines and objects appearing smaller/further away, blurred vision).

**Other** – increased risk to infections, previous infections such as tuberculosis (TB) may reoccur more easily.

### 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](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 out of the sight and reach of children. Store below 25°C in a dry place and protect from light.

Do not use this medicine after the expiry date stated on the carton. 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 dispose of 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 1mg of the active ingredient.
- The tablet also contains lactose monohydrate, maize starch, povidone, purified talc, colloidal anhydrous silica, magnesium stearate.

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

Prednisolone are white, circular, flat bevelled edge tablets.  
Pack sizes are 28.

### Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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Package leaflet: Information for the patient

# Prednisolone 1mg Tablets

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). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have an **infection** that affects your whole body (systemic infection), which is not already being treated (such as measles, chickenpox or shingles)
- if you are suffering from a **herpes** infection of the eye.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Prednisolone 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.

**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.

## Warnings and precautions

### Talk to your doctor, pharmacist or nurse before taking Prednisolone Tablets, especially if:

- you have or 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
- you have or have ever had **mental problems** such as 'depression' or 'psychoses'
- you have **epilepsy** (fits)
- you or anyone in your family has **diabetes**
- you have **high blood** pressure
- you have **kidney, liver** or **heart** problems
- you have brittle or weak bones called **osteoporosis**
- you are receiving treatment for a condition called myasthenia gravis (**a rare muscular disorder**)
- you have ever had **blood clots** (deep vein thrombosis or thromboembolism)
- you or anyone in your family has an eye problem called **glaucoma**
- you have or have ever had a **stomach ulcer**
- you have or have ever had a bad reaction such as muscle weakness to any **steroid**
- you have been in contact with anyone who has chickenpox, shingles or measles. **Contact your doctor immediately for advice**
- you have or have ever had '**tuberculosis**' (TB)
- you are receiving any **vaccines** (please see below, "Vaccinations")
- you 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.

If any of the above applies to you or if you are not sure, talk to your doctor before taking this medicine. Your doctor may want to see you more often during your treatment.

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

### 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 your 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 Tablets can cause reduced growth in infancy, childhood and adolescence, therefore long-term treatment should be avoided when possible. The growth and development of infants and children should be closely monitored. Talk to your doctor for further information.

### Elderly

Close clinical supervision is required to avoid life threatening reactions. Talk to your doctor for further information.

### Other medicines and Prednisolone Tablets

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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).

Prednisolone Tablets and some other medicines can affect the way each other work. In particular, tell your doctor if you are taking any of the following:

- medicines to relieve indigestion and heartburn
- medicines for thinning your blood (such as warfarin)
- medicines for diabetes (such as insulin)
- medicines for epilepsy (such as carbamazepine, phenobarbital and phenytoin)
- medicines for high blood pressure (such as furosemide and bendroflumethazide)
- medicines which contain oestrogens including oral contraceptives (the 'pill')
- medicines to treat infections (such as tetracyclines, rifabutin, rifampicin, erythromycin, troleandomycin and ketoconazole – used in fungal infections)
- medicines to treat asthma (such as salbutamol and salmeterol)
- anti-inflammatory medicines (including indomethacin, aspirin and ibuprofen)
- ciclosporin – used to suppress the immune system
- methotrexate – used to treat a variety of illnesses such as arthritis
- mifepristone – used for abortion
- retinoids (for skin conditions).

## Vaccinations

If you have just had any injections or vaccinations, tell your doctor before you take Prednisolone Tablets. If you are going to have any injections or vaccinations, tell your doctor or nurse that you are taking Prednisolone Tablets. This includes those needed for a foreign holiday. Some vaccines should not be given to patients taking Prednisolone Tablets. This is because Prednisolone Tablets can affect the way some vaccines work. Talk to your doctor if you are not sure.

### 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.

### 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 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, as it contains lactose.

## 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 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.

### The recommended dose is:

**Adults** - 20-40mg daily initially up to 80mg daily, reducing to a maintenance dose of 5-20mg daily.  
**Children and adolescents** - Children do not take as many tablets as adults. Your doctor will suggest the correct number of tablets for them to take.

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 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 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 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 stop taking Prednisolone Tablets

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.

If you suddenly stop taking your medicine the following side effects can occur: lack of appetite, feeling sick, being sick, tiredness, skin peeling, inflammation of the inside of the nose, inflammation (swelling and redness) of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids), muscle or joint pain, fever, headache, weight loss, painful itchy skin lumps or low blood pressure. If you notice any of these symptoms please contact your doctor as soon as possible.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may experience side effects particularly when you first start taking this medicine. Talk to your doctor or pharmacist if you notice any of the following effects or any effects not listed in this leaflet.

**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.