

Package leaflet: Information for the user

PREDNISOLONE 1 mg AND 5 mg TABLETS

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.

PREDNISOLONE TABLETS LEAFLET - HEADLINES

- **Prednisolone tablets are 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 tablets can cause side effects in some people** (see 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 (see 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.

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 – benefit information.

Prednisolone tablets contain the active substance prednisolone. 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 the 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 and nervous system
- skin conditions
- some infections
- some cancers, including leukaemia, lymphoma and myeloma
- to prevent organ rejection after a transplant

Also:

- to make up the difference when the body's production of cortisone is too low to maintain good health.
- 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)
- if you have an infection unless it is being treated with a specific antibiotic
- if you are suffering from herpes infection of the eye
- if you are suffering from galactose or lactose intolerance or glucose-galactose malabsorption.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolone tablets

- if you have ever had severe depression or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Prednisolone
- if any of your close family has had these illnesses
- if you have osteoporosis (weakened bones), particularly if you are past the menopause (the change of life), or have you suffered from muscle weakness during previous treatment with corticosteroids
- if you have stomach ulcers
- if you have heart, liver or kidney problems, or have high blood pressure
- if you have ever suffered from tuberculosis
- if you suffer from diabetes, or if anyone in your family suffer from diabetes
- if you have glaucoma (abnormally high pressure in the eyes), or if any of your family suffer from glaucoma
- if you are epileptic
- if you have ever had any psychiatric problems, or there is a family history of such problems
- if you are receiving treatment for a condition called myasthenia gravis (a rare muscle weakness disorder)
- if you have ever had blood clots (for example deep vein thrombosis (DVT), or, thromboembolism
- if you are elderly and have low potassium levels in your blood or are susceptible to infections or thinning of the skin
- if you have had a recent immunisation or vaccination

- if you have never had measles, chickenpox or shingles
- if you 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)
- if you suffer from hypothyroidism (an underactive thyroid gland which can cause tiredness or weight gain)
- if you have Duchenne's muscular dystrophy
- if you have inflammatory bowel disease such as Crohn's disease
- if you have an eye disease caused by fluid build-up at the back of the eye that causes visual impairment
- if you are undergoing immunosuppression therapy for example in the treatment of cancer
- if 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.

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

If any of these applies to you while taking Prednisolone tablets, you must tell your doctor immediately.

Important things to remember while you are taking this medicine:

- You will be given a '**steroid treatment**' card which has essential details about your treatment. **Carry this card with you at all times** whilst you are taking this medicine.
- Because it is important for doctors, dentists or other healthcare workers to know you are on steroid treatment be sure to **keep your steroid card with you at all times**.
- **Always show the card** to any doctor, dentist, pharmacist, nurse or anyone else who is about to give you treatment. Even when you have stopped the course of treatment, tell them that you have been taking steroids.
- If you have not received a steroid card, ask your doctor or pharmacist.
- If you need to **have a vaccination** whilst you are taking this medicine, make sure you tell the doctor or nurse you are taking Prednisolone tablets, as **you should not receive live vaccines**, and other vaccines may be less effective.
- **DO NOT** stop taking Prednisolone tablets without consulting your doctor first as stopping this medicine suddenly may lead to withdrawal effects (**see section 3**).

Mental problems while taking Prednisolone tablets

Mental health problems can happen while taking steroids like Prednisolone (see section 4).

- 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.

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)
- antifungals such as ketoconazole and amphotericin which are used to treat fungal infections
- diuretics (“water tablets”) including acetazolamide
- indometacin (an anti-inflammatory used for arthritis)
- anti-bacterials e.g. rifampicin, rifabutin, erythromycin, rifamycin
- carbenoxolone (used to treat ulcers)
- hypoglycaemic agents e.g. glibenclamide or insulin (used for diabetes)
- antihypertensives e.g. methyldopa
- carbamazepine, phenobarbital, phenytoin or primidone (anti-convulsants)
- aminoglutethimide (used to treat advanced breast cancer)
- anti-coagulants e.g. warfarin
- oestrogens, for example in the contraceptive pill or HRT
- salbutamol, formoterol, bambuterol, fenoterol, ritodrine, salmeterol and terbutaline used to treat asthma
- salicylates such as aspirin
- 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
- mifepristone, used to induce labour or abortion
- cytotoxic drugs for example methotrexate which is used to treat cancer
- somatotropin which is a growth hormone
- theophylline which is used for asthma and chronic obstructive pulmonary disease (COPD)
- antithyroids such as carbimazole
- isoniazid which is used to treat tuberculosis
- antacids such as magnesium trisilicate or aluminium hydroxide, used to treat the symptoms of heartburn and indigestion
- antimuscarinics/ anticholinergics such as atropine sulfate
- immunosuppressants which dampen down the activity of the body’s immune system
- 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
- liquorice can delay the clearance of prednisolone.

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

Prednisolone tablets are not expected to affect your ability to drive or operate machinery. If you feel dizzy or tired after taking Prednisolone Tablets do not drive or operate machinery until these effects have worn off.

Prednisolone tablets contain lactose

Prednisolone tablets contain **lactose**. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Prednisolone tablets

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

The tablets should be swallowed preferably with a drink of water.

Different illnesses require different doses of Prednisolone Tablets. Depending on your illness your daily dose may be between 5 and 60 mg. Your doctor will decide when and how to treat you with Prednisolone Tablets

The recommended dose is:

- **Adults and the elderly**

Initially, up to 20 mg daily in divided doses. Your doctor may prescribe up to 60 mg in severe conditions.

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.

The initial dose will normally be reduced to the lowest effective maintenance dose as soon as possible. The recommended maintenance dose is 2.5 to 15 mg daily.

In some cases, your doctor will tell you to take the tablets every other morning.

- **Use in children**

Prednisolone tablets are only used to treat children if considered essential by their doctor.

The dose will be a proportion of the adult dose according to the age of the child.

- **Children over 12 years**

Three quarters of the adult dose

- **Children over 7 years**

One half of the adult dose

- **Children over 1 year**

One quarter of the adult dose

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.

- **Use in 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 any of the following occur tell your doctor straight away:

- **Infections:** If you think you might have an infection. You are more likely to develop illnesses due to infection whilst you are taking Prednisolone Tablets. Also any existing infections may become worse. This is especially so during periods of stress. Certain infections can be serious if not controlled.
- **Chickenpox and Shingles:** If you, anyone in your family or regular contacts catch chickenpox or shingles. This is because you may become very ill if you get chicken pox whilst taking Prednisolone Tablets and for up to 3 months after you have stopped taking Prednisolone Tablets. Do not stop taking Prednisolone Tablets.
- **Measles:** If you, anyone in your family or regular contacts catch measles. You should avoid contact with people who have measles.

If you take more Prednisolone tablets than you should

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets contact your nearest hospital casualty department or your doctor immediately.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Prednisolone tablets

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Prednisolone tablets

DO NOT suddenly stop taking your Prednisolone tablets as this may lead to withdrawal syndrome which causes fever, muscle and bone pain, runny nose and eyes, painful itchy skin with nodules, and weight loss which may result in low blood pressure and death. Your doctor will tell you to reduce your dose gradually to avoid these effects.

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

4. Possible side effects

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

Serious side effects:

Stop taking Prednisolone tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

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

- Steroids including prednisolone 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 include:
 - feeling depressed, including thinking about suicide
 - feeling high (mania) or moods that go up and down
 - feeling anxious, irritability, having problems sleeping, difficulty in thinking or being confused and losing your memory
 - feeling, seeing or hearing things which do not exist. Abnormal feeling of wellbeing, feeling of dependency on treatment. Having strange and frightening thoughts, changing how you act or having feelings of being alone
- heart problems which can cause shortness of breath
- increased number of white blood cells
- thromboembolism (blood clot)
- pancreatitis (nausea, vomiting, abdominal pain and back pain)
- thinning of the skin and delayed healing, bruising, stretch marks, itching, patches of reddening skin and acne.

If you notice any of these problems keep taking your tablets, but **talk to a doctor straight away**.

Other side effects

The following side effects have also been reported. If you feel unwell with any of these side effects tell your doctor:

Not known: frequency cannot be estimated from the available data

- indigestion/heartburn, stomach ulcers with bleeding or perforation, bloating, diarrhoea, oesophageal (gullet) ulcers
- raised pressure in brain (which can cause headaches, nausea and vomiting)
- weakness and wasting of the upper arm and leg muscles, brittle bones, thinning or wasting of the bones, bone fractures and tendon rupture
- salt and water retention, high blood pressure, a change in the mineral balance in the blood
- increased sweating
- reduction in the balance between certain hormones
- in infants, children and adolescents, normal growth may be slowed or stopped, which may be irreversible
- absence or irregular menstrual periods
- a rounder shaped face
- excessive hair growth
- increased appetite, weight gain
- carbohydrate imbalance requiring anti-diabetic therapy
- reduction of nitrogen and calcium in the blood
- recurrence of tuberculosis, thrush infections
- dizziness
- vision loss
- pressure on the nerve to the eye (sometimes in children after stopping treatment)
- abnormally high pressure in the eye (glaucoma), swelling of the optic disc
- whitening or clouding of the lens (cataracts), thinning of the eye tissue (sclera and cornea)
- worsening of viral and fungal eye infections
- worsening of epilepsy
- fatigue and general feeling of being unwell
- increased cholesterol or fat levels in blood.
- 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.
- Blurred vision
- 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.
- slow heart rate

Withdrawal Symptoms: anorexia, nausea, vomiting, lethargy, headache, fever, joint pain, peeling of skin, muscle pain, inflammation of nose, conjunctivitis, painful itchy skin nodules, loss of weight and/or hypotension

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 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 this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package. Do not transfer them to another container. 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 tablets contain:

- The active ingredient is prednisolone 1 mg or 5 mg.
- The other ingredients are lactose monohydrate, dextrin, maize starch and stearic acid (E570).

What Prednisolone tablets looks like and contents of the pack:

- Prednisolone 1 mg are white biconvex tablets. Engraved: 'APS' over '2401' on one side and plain on the reverse.
- Prednisolone 5 mg are white biconvex tablets. Engraved: 'APS' breakline '2402' on one side and plain on the reverse.
- The 1 mg tablets are available in packs of 28, 56, 60, 84, 90, 100, and 500.
- The 5 mg tablets are available in packs of 28, 30, 500, 1000 and 10 x 50
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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