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Package leaflet: Information for the user

Prednisolone 1 mg Tablets  
Prednisolone 5 mg Tablets  
Prednisolone

- **Prednisolone Tablets 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 Tablets can cause side effects in some people** (read section 4 'Possible Side Effects' 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 'Possible Side Effects' 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**.

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

The name of your medicine is Prednisolone 1 mg Tablets or Prednisolone 5 mg Tablets. They contain the active ingredient called prednisolone.

Prednisolone Tablets belongs to a group of medicines called steroids. Their full name is corticosteroids. 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.

Prednisolone Tablets are used to treat 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

Check with your doctor first

- If you have ever had severe depression or manic-depression (bipolar disorder). This includes having had depression before or while taking steroid medicines like Prednisolone Tablets;
  - If any of your close family has had these illnesses.
- If either of these applies to you, talk to a doctor before taking 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);
- Are suffering from a serious infection which is not being treated;
- Are suffering from a herpes infection of the eye.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine 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;
  - 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.
  - 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 Tablets (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.
- Contact your doctor if you experience blurred vision or other visual disturbances

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.

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, especially any of the following medicines as they may affect, or be affected by Prednisolone Tablets:

- 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)
- Drugs for diabetes including insulin;

- Antifungals such as ketoconazole and amphotericin which are used to treat fungal infections;
- Ciclosporin which is used to treat rheumatic disease, skin complaints or after a transplant;
- Antibiotics such as erythromycin, troleandomycin and rifamycin which are used to treat bacterial infections;
- Cardiac glycosides for example digoxin which is used to help strengthen a weak heart;
- Antiepileptic drugs such as carbamazepine, phenobarbital, phenytoin and primidone which are used to treat epilepsy;
- Non-steroidal anti-inflammatory drugs (NSAIDs) for example aspirin, ibuprofen and indomethacin used for pain relief or to treat rheumatic disease;
- Oestrogens, for example in the contraceptive pill or HRT;
- Mifepristone, used to induce labour or abortion;
- Thiazide diuretics ("water tablets") for example bendroflumethiazide used for water retention or high blood pressure;
- Cytotoxic drugs for example methotrexate which is used to treat cancer;
- Medicines to treat high blood pressure;
- Vaccinations: You must tell your doctor or nurse that you are taking a steroid before you are given any vaccinations as some vaccines should not be given to individuals taking prednisolone.
- Steroids affect your immune response and you must not be given anticoagulants for example warfarin which is used to thin the blood. Your INR or prothrombin time may be closely monitored if you are taking anticoagulants;
- Somatropin which is a growth hormone;
- Carbenoxolone which is used for ulcers;
- Acetazolamide which is used in the treatment of glaucoma and epilepsy;
- Salbutamol, formoterol, bambuterol, fenoterol, ritodrine, salmeterol and terbutaline used to treat asthma;
- Loop diuretics for example furosemide which is used to treat heart failure;
- Antimuscarinics/ anticholinergics;
- Theophylline which is used for asthma and chronic obstructive pulmonary disease (COPD);
- Immunosuppressants which dampen down the activity of the body's immune system;
- Antithyroids such as carbimazole;
- Antacids such as magnesium trisilicate or aluminium hydroxide, used to treat the symptoms of heartburn and indigestion;
- Isoniazid which is used to treat tuberculosis;
- Rifampicin and rifabutin which are used to treat tuberculosis and other bacterial infections;
- Aminoglutethimide which is used to treat some cancers.

Prednisolone Tablets with food and drink

Prednisolone Tablets should be swallowed with water. You can take Prednisolone Tablets before or after a meal. Avoid eating liquorice whilst taking Prednisolone Tablets.

Pregnancy, breast-feeding and fertility

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. 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. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

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

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

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

Prednisolone 5 mg tablet can be divided into equal doses.

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240mm

296mm

10mm

10mm

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Different illnesses require different doses of Prednisolone Tablets. Depending on your illness your daily dose may be between 5 and 60 mg. 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.

**Stop taking Prednisolone Tablets:** It is important to discuss your treatment with your doctor before stopping treatment. Sudden stopping of treatment can cause the following symptoms: loss of appetite, nausea, vomiting, tiredness, headache, fever, painful muscles and joint pains, peeling and loss of skin, inflammation of the eyes and nasal passages, painful and itchy skin lumps, loss of weight and/or low blood pressure.

**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.

**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 catches chickenpox or shingles. This is because 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 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 catches measles. You should avoid contact with people who have measles. 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 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.

**If you take more Prednisolone Tablets than you should**

If you accidentally take too many Prednisolone Tablets or someone else takes any of your medicine you should, contact your doctor or nearest hospital emergency department immediately. Show any left-over medicines or the empty packet to the doctor.

**If you forget to take Prednisolone Tablets**

If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose. Then go on as before.

**4. Possible side effects**

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

**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.

**Serious effects: tell a doctor straight away**

- Inflammation of the pancreas (very severe abdominal pains);
- Painful skin ulcers.

**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.

- 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.

If you notice any of these problems talk to a doctor straight away.

**Other side effects you may experience:**

- Tiredness;
- Blood clotting;
- Heart problems which can cause shortness of breath;
- Convulsions;
- Vertigo;
- Raised pressure in the brain (which can cause headaches, nausea and vomiting);
- Sleeplessness;
- Worsening of schizophrenia;
- Risk of stroke is increased in horton disease;
- Increased pressure in the eyeball (glaucoma);
- Whiteness 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;
- Bruising;
- Patches of skin reddening;
- Rash;
- Acne;
- Slow healing of wounds;
- 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;
- 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;
- Bone fractures;
- Face becomes very round;
- Increased blood sugar;
- Euphoria (feeling high);
- Depression;
- 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;
- High blood pressure (hypertension);
- A change in the levels of some hormones, mineral balance or protein in blood tests;
- Increased cholesterol or fat levels in blood;
- Irritability;
- Accumulation of fat tissue on localised parts of the body, manifesting as different presentations for example back pain or weakness (epidural lipomatosis);
- Increased number of white blood cells;
- Nausea and vomiting;
- Vision problems;
- Worsening of epilepsy;
- Thinning of the skin;
- Stretch marks;
- Itching;
- Hives;
- Extra hair growth;
- Increased sweating;
- General unwell feeling;

- Diabetes or worsening of existing diabetes;
- Inflammation and ruptures of tendons
- 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 (Frequency is not known).
- Blurred vision (frequency not known)
- Slow heart rate (Frequency Not known)

**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](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.
- Container: Do not store above 25°C. Store in the original container. Keep the container tightly closed.
- Blister packs: Do not store above 25°C. Store in the original package.
- Do not take these tablets after the expiry date shown on the pack 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 in this medicine is prednisolone.
- The other ingredients are: Lactose, Maize Starch, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid and Magnesium Stearate.

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

- Prednisolone 1 mg and 5 mg Tablets are white, circular, biconvex tablets with 'P1' on one side and plain on the reverse (for Prednisolone 1 mg Tablets) with 'P5' on one side and breakline on the reverse (for Prednisolone 5mg Tablets) respectively.
- Prednisolone 1 mg and 5 mg Tablets are available in packs of 28, 100, 250, 500 and 1000. The 5 mg tablet is also available in a pack of 5000. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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**Prednisolone 1 mg Tablets; PL 17907/0455**

**Prednisolone 5 mg Tablets; PL 17907/0456**

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To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

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