Package leaflet: Information for the user

Prednisolone 5 mg Soluble Tablets

prednisolone

- **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 this medicine for more than three 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.**

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

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1. What Prednisolone 5 mg Soluble Tablets are and what they are used for

The name of your medicine is Prednisolone 5 mg Soluble Tablets. This medicine contains the active ingredient prednisolone which belongs to a group of medicines called corticosteroids or "steroids".
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. You must take this medicine regularly to get maximum benefit from it.
Steroids work by reducing inflammation and lowering the body's immune response.

Prednisolone 5 mg Soluble Tablets are used to treat a variety of inflammatory diseases including severe asthma, rheumatoid arthritis, allergic reactions, bowel diseases, severe skin conditions, kidney disorders and some blood disorders.

2. What you need to know before you take Prednisolone 5 mg Soluble Tablets

Do not take Prednisolone
- if you are **allergic** to prednisolone or any of the other ingredients of this medicine (listed in section 6). (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing)
- if you have recently had a **vaccination** or have a vaccination planned
- if you have a viral **infection** such as **measles**, **chicken pox or shingles**, or any other infection. Tell your doctor **immediately** if you have come into contact with anyone suffering with measles, chicken pox or shingles in the last three months.

If any of the above affects you, do not take prednisolone. If you are unsure ask your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Prednisolone 5 mg Soluble Tablets if you have or ever had:
- **severe depression** or manic-depressive illness (bipolar disorder). This includes having had depression before while taking steroid medicines like Prednisolone 5 mg Soluble Tablets or if anyone in your family has suffered from these illnesses
- TB (tuberculosis)
- diabetes
- epilepsy
- depression or other mental illness
- an eye disease caused by a rise of pressure within the eye (glaucoma)
- osteoporosis (thinning of the bones)
- muscle problems when steroids have been taken before
- stomach ulcers
- high blood pressure, heart failure or recently suffered a heart attack
- any liver or kidney problems
- an under-active thyroid (hypothyroidism)
- 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 you are not sure please tell your doctor or pharmacist before you use this medicine.

Mental health problems while taking prednisolone
Mental health problems can occur while taking steroids like prednisolone (see also section 4 Possible Side Effects).
- these illnesses can be severe
- 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 occur they might need treatment.

Talk to a doctor if you (or someone taking this medicine) show any signs of mental health problems. This is particularly important if you are depressed or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or the medicine stopped altogether.

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 which may be irreversible.

Other medicines and Prednisolone 5 mg Soluble Tablets
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

This is especially important if you are taking:
- medicines for **epilepsy** such as carbamazepine, phenobarbitone, phenytoin or primidone
- **antibiotics** such as rifampicin, rifabutin, erythromycin
- **mifepristone** (used to terminate pregnancy)
- oral contraceptives
- somatropin (used to treat growth problems)
- medicines for **diabetes** such as insulin, glibenclamide or metformin
- medicines to treat **high blood pressure**, such as diuretics (water tablets) like bendroflumethiazide and furosemide
- **warfarin** or other medicines used to thin the blood
- **aspirin** or **Non Steroidal Anti-Inflammatory Drugs** (e.g. ibuprofen)
- medicines to treat **fungal infections** such as amphotericin, ketoconazole
- acetazolamide (used to treat glaucoma)
- carbenoxolone (used to treat stomach ulcers)
- **aminoglutethimide, methotrexate** (used for rheumatoid arthritis, psoriasis and certain types of cancer)
- any medicine which belong to a group of medicines called sympathomimetics (e.g. ephedrine (a nasal decongestant))
- medicines used to treat myasthenia gravis
- medicines used to make x-rays clearer
- ciclosporin (used to stop the body rejecting bone marrow or organ transplants)
- **medicines used to treat asthma** (e.g. theophylline, bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline).
- some medicines may increase the effects of Prednisolone 5 mg Soluble Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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.

Driving and using machines
This medicine should not affect your ability to drive or use machines.

Carrying a Steroid card
Your doctor or pharmacist will have given you a **Steroid Treatment Card** with your prescription or medicine.
YOU SHOULD ALWAYS CARRY THIS CARD WITH YOU as it must be shown to any of the following persons:
Doctor or Nurse - before having any surgery or emergency treatment or if any new treatment is prescribed.
Dentist - before having any dental surgery.
Pharmacist - before buying any medicine.
Optician - it is advisable to have regular eye tests.

Prednisolone 5 mg Soluble Tablets contain sodium benzoate
This medicine contains 7.5 mg benzoate salt in each tablet. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Prednisolone 5 mg Soluble Tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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3. How to take Prednisolone 5 mg Soluble Tablets

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

The recommended dose is:
Adults:
The dose will depend on the condition you are being treated for and can vary between 10 mg and 100 mg daily. Your doctor will always reduce the dose to the smallest dose that works for you.

Use in children and adolescents
To treat asthma attacks:
Children above 2 years - the doctor will decide the most appropriate dose to treat your child.
Children under 2 years - may be treated in the hospital.
Treatment for up to three days is usually enough, but may be longer.

Method of administration:
The tablets can be swallowed whole, but they are **best taken as a drink** after dissolving them in a glass of water. Take your tablets as a single dose each morning, unless your doctor has told you otherwise.

If you take more Prednisolone 5 mg Soluble Tablets than you should
If you take more Prednisolone 5 mg Soluble Tablets than you should, contact your doctor or nearest hospital emergency department **immediately**. Remember to take this leaflet and/or the package with you to show the doctor what you have taken.

If you forget to take Prednisolone 5 mg Soluble Tablets
If you forget to take Prednisolone 5 mg Soluble Tablets, take the next dose 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.

If you stop taking Prednisolone 5 mg Soluble Tablets
Do not stop taking the tablets unless you have been told to do so by your doctor, even if you feel better, as it can make you ill. It can cause withdrawal symptoms such as fever, sickness, pain in the muscles and joints, runny nose, sore, red and sticky eyes (conjunctivitis), itchy skin and weight loss.

Talk to your doctor if you want to stop taking the tablets – your doctor may want to reduce your dose gradually.

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. Steroids including prednisolone can cause severe mental health problems.

These are common in both adults and children. They can affect about five in every 100 people taking medicines like prednisolone.
- feeling depressed, including thinking about suicide
- feeling high (mania) or having moods that go up (euphoric mood) and down
- feeling anxious, having problems sleeping, having 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 immediately.**

If you notice;
- itching or skin rashes
- swelling of the face, lips or throat
- difficulty in breathing or wheeziness.

Stop taking the tablets and tell your doctor immediately.
These may be signs of an allergic reaction.

The side effects which can occur if steroids are given in high doses for a long time are:
Not known (frequency cannot be estimated from the available data)
- generally feeling unwell
- feeling sick (nausea)
- hiccups
- indigestion or stomach discomfort
- stomach ulcer (which can rupture and bleed) or ulcer in the oesophagus (gullet)
- thrush
- inflammation of the pancreas causing abdominal pain (pancreatitis)
- muscle weakness
- muscle pain
- thinning of bones which makes fractures more likely (osteoporosis)
- damage to tendons
- joint stiffness causing limited movement, pain and muscle spasms
- fluid retention causing swelling
- feeling dehydrated
- high blood pressure
- slow healing of wounds, thinning of the skin, bruising, acne, marks which look like stretch marks
- small red, purple or blue spots found along the surface of the skin (caused by blood vessels under the skin)
- low adrenal gland function
- slowed growth in infants, children and teenagers
- irregular or stopped menstrual periods
- swollen, round face (Cushingoid facies)
- excess hair growth
- increased appetite and weight gain
- intolerance to carbohydrates
- loss of protein and calcium balance
- dizziness
- severe headaches with blurred vision or temporary visual problems in children (usually after stopping treatment)
- worsening of epilepsy
- raised pressure in the eyes (glaucoma), cataracts, thinning and inflammation of the cornea (part of the eye), worsening of viral or fungal eye diseases
- sensation of spinning (vertigo)
- heart attack (sudden severe chest pains)
- slow heart rate
- changes in body chemistry (sodium and potassium salts)
- an increase in the number of white blood cells
- formation of blood clots
- 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 long term use of high dose steroids, may lead to a weakening of the immune system, which can increase the risk of malignancy.

Kaposi's sarcoma (a type of cancer consisting of raised, red, purple or brown skin lesion) has also been reported to occur in patients receiving corticosteroids. Stopping treatment may alleviate these symptoms.

Prednisolone 5 mg Soluble Tablets can make it easier for you to pick up infections which may very rarely be fatal. Infections such as chicken pox and measles can be made worse or TB (tuberculosis) may recur.

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 Yellow Card Scheme Website: 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 5 mg Soluble Tablets

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Store in the original package in order to protect from light.

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 5 mg Soluble Tablets contain
- The active substance is prednisolone. Each soluble tablet contains 5 mg of prednisolone (as prednisolone sodium phosphate).
- The other ingredients are sodium bicarbonate, sodium acid citrate, saccharin sodium, povidone (K-30), erythrosine (E 127) and sodium benzoate.

What Prednisolone 5 mg Soluble Tablets look like and contents of the pack

Prednisolone 5 mg Soluble Tablets are pink, round, approximately 7mm, flat, bevelled edged, uncoated soluble tablet having break line on one side and plain on other side. The tablet may be mottled.

Prednisolone 5 mg Soluble Tablets are available in triple laminated cold form (Alu-Alu) blister pack.

Pack Size: 30 Soluble Tablets

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