

Package leaflet: Information for the user

Prednisolone 5mg Soluble Tablets prednisolone

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prednisolone Soluble Tablets are and what they are used for
2. What you need to know before you take Prednisolone Soluble Tablets
3. How to take Prednisolone Soluble Tablets
4. Possible side effects
5. How to store Prednisolone Soluble Tablets
6. Contents of the pack and other information

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

Your doctor has decided that you or your child, need this medicine to help treat your or their, condition.

Prednisolone 5mg Soluble Tablets (called Prednisolone Soluble Tablets throughout the rest of this leaflet) contain the active ingredient prednisolone. Prednisolone belongs to a group of medicines called steroids (the full name is corticosteroids).

Corticosteroids occur naturally in the body and help to maintain health and wellbeing. Boosting your body with extra corticosteroid (such as prednisolone) is an effective way to treat various illnesses involving inflammation in the body.

Prednisolone Soluble Tablets reduce 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 Soluble Tablets can be used:

- to treat breathing difficulties associated with asthma;
- to treat severe allergic reactions;
- to treat illnesses which cause inflammation of the skin, small and medium sized arteries, muscles and joints (including rheumatoid arthritis);
- to treat problems with your immune system, where the immune system attacks the cells in your body;
- to treat certain kidney problems;
- to treat certain illnesses resulting in inflammation of the bowels e.g. ulcerative colitis or Crohn's disease;
- to treat inflammation of the heart;
- to treat problems with your blood including haemolytic anaemia (a disorder which breaks down red blood cells) and leukaemia;
- to prevent rejection following an organ transplant.

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

Do not take Prednisolone Soluble Tablets

- if you are allergic to prednisolone or any of the other ingredients of this medicine (listed in section 6). Signs of a severe allergic reaction may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away;**
- if you have an infection which affects your entire body (unless you are receiving treatment for the infection);
- if you have recently had any “live” vaccinations;
- if you have a herpes simplex eye infection.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Prednisolone Soluble Tablets

- 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 Soluble Tablets;
- if any of your close family has had these illnesses.
- 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.

Mental health problems while taking Prednisolone Soluble Tablets

Mental health problems can happen while taking steroids like Prednisolone Soluble Tablets.

- 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 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 stopped.

Chickenpox, shingles or measles

- Tell your doctor if you have previously had chickenpox, shingles or measles or if you have been vaccinated against these infections.
- It is important that whilst you are taking this medicine, you avoid contact with anybody who has chickenpox, shingles or measles especially if you have not already had them. If you think you may have come into contact with a person who has chickenpox, shingles or measles, **you should contact your doctor immediately.**
- If you catch chickenpox, shingles or measles, **tell your doctor immediately.** Your doctor will advise you on how to take prednisolone. You may be told to increase the number of tablets that you take.

Please also tell your doctor or pharmacist if any of the following apply to you:

- if you have or have ever had, tuberculosis (TB) or blood poisoning (septicaemia);
- if you have liver or kidney problems;
- if you have high blood pressure (or a family history of high blood pressure), heart disease or you have recently had a heart attack;
- if you have or have a family history of the following:
 - diabetes
 - osteoporosis
 - glaucoma (raised eye pressure)

- epilepsy (fits)
- if you have ever previously suffered from muscle weakness when using prednisolone or any other steroids, in the past;
- if you have or have had, a stomach ulcer;
- if you have an underactive thyroid gland.

If you have any of the above conditions, your doctor may monitor you carefully whilst you are taking this medicine.

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 Soluble Tablets

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

- Some medicines may increase the effects of Prednisolone Soluble Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- **Rifampicin and rifabutin** (antibiotics used to treat tuberculosis).
- **Carbamazepine, phenytoin, primidone and phenobarbitone** (for epilepsy).
- **Ephedrine** (a nasal decongestant).
- **Aminoglutethimide, methotrexate** (anti-cancer treatment).
- **Mifepristone** (used for termination of pregnancy).
- **Erythromycin** (an antibiotic, used to treat infections).
- **Ketoconazole, amphotericin** (used to treat fungal infections).
- **Ciclosporin** (used to prevent rejection after transplants).
- **Oestrogen hormones** including the **contraceptive pill**.
- **Medicines for diabetics (such as insulin)**.
- **Medicines used to treat high blood pressure** (e.g. hydralazine).
- **Diuretics** also known as water tablets (e.g. furosemide, bendrofluzide).
- **Somatotropin** (a growth hormone).
- **Medicines used to treat myasthenia gravis** (muscle weakness), such as neostigmine.
- **Medicines used to make x-rays clearer**.
- **Anticoagulant medicines which thin the blood** (e.g. warfarin and coumarin).
- **Aspirin and Non-Steroidal Anti-Inflammatory Drugs** (e.g. ibuprofen).
- **Salicylates** (e.g. Aspirin).
- **Acetazolamide** (used for glaucoma and epilepsy).
- **Carbenoxolone** (used in the treatment of stomach ulcers).
- **Medicines used to treat asthma** (e.g. theophylline, bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline).

Vaccinations

If you have recently had or are planning to have any vaccinations, tell your doctor before taking Prednisolone Soluble Tablets. This is because some injections or vaccinations should not be given to people who are taking prednisolone.

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.

Prednisolone Soluble Tablets contain sodium and sodium benzoate

- This medicinal product contains 37.6 mg of sodium (main component of cooking/table salt) per in each tablet. This is equivalent to 1.88% of the recommended maximum daily dietary intake of

sodium for an adult. To be taken into consideration by patients on a controlled sodium (salt) diet. Talk to your doctor or pharmacist if you need 11 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

- This medicine contains 4 mg sodium benzoate (E 211) in each tablet. Sodium benzoate (E 211) may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Carrying a Steroid card

If you take this medicine for more than three weeks, your doctor or pharmacist will give you a **Steroid Treatment Card** with your prescription or medicine.

- Keep this card with you always.
- Show it to any doctor, dentist, nurse, midwife or anyone else who is giving you treatment.
- Even after your treatment has finished, tell any doctor, dentist, nurse, midwife or anyone else who is giving you treatment that you have taken steroids.

3. How to take Prednisolone Soluble Tablets

Your doctor will decide on the most appropriate dose to treat you or your child.

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 usual starting dose is two tablets (10mg prednisolone) to twenty tablets (100mg prednisolone) per day.
- Your doctor may reduce the dose, after a few days or weeks, depending on how well your condition is responding to the treatment.

For Rheumatoid Arthritis

- The usual starting dose is between one and a half to two tablets (7.5mg to 10mg prednisolone) per day.

Use in children and adolescents

- Your doctor will decide the most appropriate dose to treat your child.
- If Prednisolone Soluble Tablets have been prescribed for your child, for the treatment of acute asthma attacks the following dosing regime may be given for up to three days:
 - For children over 5 years of age, six to eight tablets (30 – 40mg prednisolone) may be prescribed;
 - For children aged 2-5 years of age, four tablets (20mg prednisolone) may be prescribed;
 - For children aged under 2 years, two tablets (10mg prednisolone) may be prescribed if your child is being treated in hospital.

Method of administration: For oral use only

- Prednisolone Soluble Tablets are best taken dissolved in a glass of water, however, they can also be taken whole, with a drink of water;
- dissolve the number of tablets, that your doctor has told you to take, in a glass of water, and then drink all of it immediately;
- do not leave your drink where someone else may drink it as your medicine could harm them;
- the tablet can be divided into equal doses.

If you take more Prednisolone Soluble Tablets than you should

If you take more tablets than your doctor has told you to, contact a doctor or your nearest hospital casualty department immediately and take this medicine with you.

If you forget to take Prednisolone Soluble Tablets

- If you forget to take a dose, take it as soon as you remember unless it is almost time for the next dose.

- Do not take a double dose to make up for a forgotten dose.

If you stop taking Prednisolone Soluble Tablets

Speak to your doctor before you stop taking Prednisolone Soluble Tablets.

- **Do not** stop taking this medicine suddenly. Your doctor will tell you how to reduce your dose slowly over a number of weeks or months to help lower the chance of you getting withdrawal symptoms.
- Stopping Prednisolone Soluble Tablets (particularly if stopped suddenly) can lead to **withdrawal symptoms**. The most common are:
 - high temperature
 - muscle and joint pain
 - runny nose
 - weight loss
 - itchy skin
 - red, sore and sticky eyes (conjunctivitis)
 - headache
 - being sick
 - blurred vision
 - low blood pressure
- If you get severe withdrawal symptoms tell your doctor **straight away**. He/she may ask you to start taking your medicine again and then to start coming off it again more slowly.

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.

If you experience any of the following side effects after you have been given your medicine, tell your doctor or pharmacist immediately:

- **Severe allergic reaction** which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**
- **Serious mental health problems.** Steroids, including prednisolone, can cause serious mental health problems. These are common in both adults and children. They can affect about five in every 100 people using medicines like prednisolone. The symptoms include:
 - feeling depressed, including thinking about suicide;
 - feeling high (mania) or moods that can go up (euphoric mood) and down;
 - feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory;
 - feeling, seeing or hearing things that do not exist. Having strange and frightening thoughts, changing how you act or have feelings of being alone.
- **If you have epilepsy** and you have more fits than normal.

The following side effects may occur if prednisolone is given for a long period of time:

Not known: frequency cannot be estimated from the available data

- if you have had tuberculosis in the past, it may return
- you may get infections more easily than usual
- a rare type of cancer which can affect both the skin and internal organs (Kaposi's sarcoma)
- raised level of white blood cells
- facial puffiness and weight gain (Cushingoid)
- intolerance to carbohydrates which might result in a requirement for anti-diabetic treatment or you may develop a mild form of diabetes, but without any obvious symptoms

- salt imbalances or water retention in the body
- low levels of potassium in the blood, which may result in tiredness, confusion, muscle weakness or muscle cramps
- increased appetite
- loss of protein and calcium balance
- dizziness
- headache
- increased pressure in the eye, swelling in the eye, cataracts
- detachment of the retina causing visual impairment
- protrusion of the eyeballs
- thinning of the eye membranes, worsening of existing eye infections
- sensation of spinning (vertigo)
- tearing of the heart muscle tissues, particularly if you have recently had a heart attack
- heart failure in susceptible people
- slow heart rate
- high blood pressure
- blocked blood vessel (embolism)
- hiccups or indigestion
- feeling or being sick
- swollen stomach or stomach ache
- diarrhoea
- ulcers in the oesophagus (gullet)
- thrush
- inflammation of the pancreas causing abdominal pain
- stomach ulcers (which may bleed)
- thin delicate skin, unusual marks on the skin or bruising
- appearance of stretch marks
- acne
- visible swollen capillaries
- increased sweating
- rash, itching skin
- excess body hair (particularly in women)
- muscle wasting, weakness or pain
- thinning of the bones with an increased risk of fractures (osteoporosis)
- bone disease
- irregular periods or your periods may stop altogether
- slow wound healing
- generally feeling unwell
- weight gain
- breaking of tendons. Symptoms can include hearing or feeling a pop or a snap, severe pain, immediate bruising and an inability to put weight on or use, the affected area.
- 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.

Additional side effects in children and adolescents

Children and teenagers taking this medicine may grow more slowly than normal. If you, as the patient or carer, are worried about the effects of taking this medicine, go back and discuss it with your doctor.

Elderly

If you are elderly, your doctor will monitor you closely whilst you are taking this medicine as you may be more likely to experience side effects.

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. (See details below)

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 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 and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Once dissolved, drink your medicine immediately.

Do not use this medicine if you notice any visible signs of deterioration of the blister pack or the tablets. Return it to your pharmacist.

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 Soluble Tablets contain

- The active substance is prednisolone. Each tablet contains 5mg prednisolone (as the sodium phosphate ester).
- The other ingredients are sodium acid citrate, sodium hydrogen carbonate, saccharin sodium, povidone, sodium benzoate (E 211) and erythrosine (E127).

What Prednisolone Soluble Tablets look like and contents of the pack

Pink flat, round soluble tablets engraved with λ5 and break marked on the same side.

The tablets are foil strip packed and supplied in cartons of 30 tablets.

Marketing Authorisation Holder

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Manufacturer

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