

Package leaflet: Information for the user

Prednisolone 10mg/ml Oral Solution

Read all of this leaflet carefully before you or your child, starts 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 or your child 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 or your child, 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 Oral Solution is and what it is used for
2. What you need to know before you take Prednisolone Oral Solution
3. How to take Prednisolone Oral Solution
4. Possible side effects
5. How to store Prednisolone Oral Solution
6. Contents of the pack and other information

1. What Prednisolone Oral Solution is and what it is used for

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

Prednisolone 10mg/ml Oral Solution (called Prednisolone Oral Solution throughout the rest of this leaflet) contains 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 Oral Solution 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 Oral Solution 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 Oral Solution

Do not take Prednisolone Oral Solution:

- 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Prednisolone Oral Solution:

- 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 Oral Solution;
- 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.

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

Mental health problems while taking Prednisolone Oral Solution

Mental health problems can happen while taking steroids like Prednisolone Oral Solution.

- 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. Your doctor may want to change your dose of Prednisolone Oral Solution.

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.

Other medicines and Prednisolone Oral Solution

Please tell your doctor or pharmacist 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 Oral Solution 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): taking these medicines with prednisolone may stop prednisolone from working properly.
- **Carbamazepine, phenytoin, primidone** and **phenobarbitone** (for epilepsy): taking these medicines with prednisolone may stop prednisolone from working properly.
- **Ephedrine** (a nasal decongestant): taking ephedrine with prednisolone may stop prednisolone from working properly.
- **Aminoglutethimide** (anti-cancer treatment): taking this medicine with prednisolone may stop prednisolone from working properly.
- **Mifepristone** (used for termination of pregnancy): taking mifepristone with prednisolone may stop prednisolone from working properly for several days.
- **Erythromycin** (an antibiotic, used to treat infections): if taken with prednisolone, your doctor may need to change your dose of prednisolone or you may experience more side effects.
- **Ketoconazole** (used to treat fungal infections): if taken with prednisolone, your doctor may need to change your dose of prednisolone or you may experience more side effects.

- **Ciclosporin** (used to prevent rejection after transplants): if taken with prednisolone, your doctor may need to change your dose of prednisolone or you may experience more side effects.
- **Oestrogen hormones** including the **contraceptive pill**: if taken with prednisolone, you may experience more side effects and your doctor may need to change your dose of prednisolone.
- **Medicines for diabetics (such as insulin)**: if taken with prednisolone, then these medicines may not work properly.
- **Medicines used to treat high blood pressure** (e.g. hydralazine): if taken with prednisolone, then these types of medicines may not work properly.
- **Diuretics** also known as water tablets (e.g. bendrofluazide): if taken with prednisolone, then these types of medicine may not work properly.
- **Somatotropin** (a growth hormone): if taken with prednisolone, your medicine may no longer work properly.
- **Medicines used to treat myasthenia gravis** (muscle weakness), such as neostigmine: if taken with prednisolone, these medicines may not work as well.
- **Medicines used to make x-rays clearer**: if taken with prednisolone, these medicines may not work as well.
- **Anticoagulant medicines which thin the blood** (e.g. warfarin and coumarin): if taken with prednisolone, you may be at an increased risk of bleeding, therefore your doctor is likely to monitor you more closely.
- **Aspirin and Non-Steroidal Anti-Inflammatory Drugs** (e.g. ibuprofen): if taken with prednisolone you may be more likely to develop ulcers or bleeding from the stomach.
- **Salicylates** (e.g. Aspirin): if taken with prednisolone you may experience an increase in side effects of the salicylate once you stop taking prednisolone.
- **Methotrexate** (anti-cancer treatment): if taken with prednisolone you may experience more severe side effects.

In addition, please tell your doctor or pharmacist if you are taking any of the following medicines, as taking these medicines with Prednisolone Oral Solution may cause you to have a lower level of potassium in your blood than normal (hypokalaemia):

- **Acetazolamide** (used for glaucoma and epilepsy);
- **Diuretics** also known as **water tablets** e.g. furosemide and bendroflumethiazide (used to treat high blood pressure);
- **Carbenoxolone** (used in the treatment of stomach ulcers);
- **Medicines used to treat asthma** (e.g. theophylline, bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline);
- **Amphotericin** (used to treat fungal infections).

Vaccinations

If you have recently had or are planning to have any vaccinations, tell your doctor before taking Prednisolone Oral Solution. 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 Oral Solution contains sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and sodium:

- Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).
- Sodium. This medicinal product contains 3mg of sodium per 1ml oral solution (10mg prednisolone) and 30mg of sodium per 10ml of oral solution (100mg prednisolone) daily. To be taken into consideration by patients on a controlled sodium diet.

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 Oral Solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. These instructions will have been added to the dispensing label by your pharmacist.

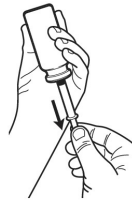
Your doctor will decide on the most appropriate dose to treat you or your child.

Using the syringe

A 5ml graduated syringe and a syringe/bottle adaptor is provided with your medicine. Use the syringe to withdraw, from the bottle, the amount of Prednisolone Oral Solution that has been prescribed for you by your doctor.

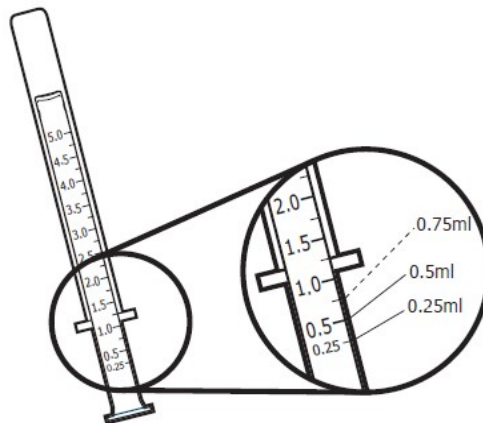
- Insert the bottle adaptor firmly into the neck of the bottle.
- Push the tip of the syringe into the hole in the top of the adaptor and ensure that it is secure.
- Hold the syringe in place and then turn the bottle upside down (refer to **Figure 1**).
- Still holding the syringe in place, pull the plunger down to the correct mark on the syringe (refer to **Figure 1** and **Figure 2**).
- Turn the bottle the right way up.
- Remove the syringe, from the adaptor, by holding onto the bottle and gently twisting the syringe.
- After use replace the bottle cap and wash the syringe in warm water. Allow to dry.
- **Do not** remove the adaptor from the bottle.

Figure 1.



Each graduation on the syringe provided is equivalent to 0.25ml of solution (refer to Figure 2).

Figure 2.



The recommended dose is:

Adults

- The usual starting dose is 1ml to 10ml 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 0.75ml and 1ml per day.

Use in children and adolescents

- Your doctor will decide the most appropriate dose to treat your child.
- If Prednisolone Oral Solution has 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, 3 to 4ml may be prescribed;
 - For children aged 2-5 years of age, 2ml may be prescribed;
 - For children aged under 2 years, 1ml may be prescribed if your child is being treated in a hospital.

Important: If you are unsure how much medicine to take, please contact your doctor or pharmacist for advice.

Method of administration: For oral use only.

If you take more Prednisolone Oral Solution than you should

If you take more oral solution 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 Oral Solution

- 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 Oral Solution

Speak to your doctor before you stop taking Prednisolone Oral Solution.

- **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 Oral Solution (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 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

- 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
- 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

via the Yellow Card Scheme at: . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prednisolone Oral Solution

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

Store in a refrigerator (2°C - 8°C).

Once opened, your medicine can be stored at a temperature below 25°C and must be used within 3 months.

Keep this medicine in the original packaging, in order to protect from light.

Do not use this medicine if you notice any visible signs of damage to the bottle or deterioration in your medicine. 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 to protect the environment.

6. Contents of the pack and other information

What Prednisolone Oral Solution contains

- The active substance is prednisolone. Each 1ml of oral solution contains 10mg prednisolone (as prednisolone sodium phosphate).
- The other ingredients are sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), glycerol, sodium saccharin, disodium edetate, sodium dihydrogen phosphate dihydrate, sodium hydroxide (as pH adjuster), orange flavour and purified water (see section 2 **What you need to know before you take Prednisolone Oral Solution**).

What Prednisolone Oral Solution looks like and contents of the pack

Prednisolone 10mg/ml Oral Solution is a clear colourless to yellowish oral solution with a characteristic odour of orange. It is available in an amber glass bottle containing 30ml of medicine. The pack also contains a 5ml plastic oral dosing syringe and an adaptor.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom.

Manufacturer

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