

Package leaflet: Information for the user

PREDNISOLONE 25MG TABLETS

Important things you need to know about Prednisolone

- **Prednisolone is a steroid medicine.** This can be 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 lower the dose gradually.
- **Prednisolone can cause side effects in some people** (read section 4 for more information). These include problems such as mood changes (feeling depressed, or 'high'), or stomach problems that 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 it for more than 3 weeks, you will be given 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, tell 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 is and what it is used for
2. What you need to know before you take Prednisolone
3. How to take Prednisolone
4. Possible side effects
5. How to store Prednisolone
6. Contents of the pack and other information

1. WHAT PREDNISOLONE IS AND WHAT IT IS USED FOR

The name of your medicine is Prednisolone 25mg Tablets (called Prednisolone throughout this leaflet). Prednisolone is a steroid medicine. Their full name is glucocorticoids.

How Prednisolone works

- 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 works by reducing this inflammation, which could otherwise go on making your condition worse.

- Prednisolone also works by stopping reactions known as autoimmune reactions. These reactions happen when your body's immune system attacks the body itself and causes damage.
- You must take this medicine regularly to get maximum benefit from it.

Prednisolone can be used to treat:

- Illnesses (sometimes called collagen disease) which cause inflammation of the skin, muscles or joints. These include rheumatic fever and systemic lupus erythematosus (SLE)
- Blood problems such as anaemia and leukaemia
- Skin and kidney problems
- Stomach problems such as ulcerative colitis

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PREDNISOLONE

Do not take this medicine if:

- You are allergic to prednisolone, or any of the ingredients in these tablets (listed in section 6) Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have an infection that affects your whole body (systemic infection), which is not already being treated

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking prednisolone.

Warnings and precautions

Talk to your doctor before you take prednisolone if:

- You have ever had severe depression or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like prednisolone.

- Any of your close family has had these illnesses.
- You have or ever had mental problems such as 'depression' or 'psychoses'

If any of the above applies to you, talk to a doctor before taking prednisolone.

Mental problems while taking prednisolone

Mental health problems can happen while taking steroids like prednisolone (see also 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.

Tell your doctor before taking this medicine if you:

- have epilepsy (fits)
- or anyone in your family has diabetes
- have high blood pressure
- have kidney, liver or heart problems
- have brittle or weak bones (osteoporosis)
- or anyone in your family has an eye problem called glaucoma
- have or ever had a stomach ulcer or ulceration of the gut
- have or ever had an infection caused by a virus or fungus. This includes infections such as athlete's foot, thrush, and cold sores
- have or ever had tuberculosis (TB)
- have or are suspected of having pheochromocytoma - a tumor of the adrenal gland
- 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.

If any of the above apply to you, your doctor may want to see you more often during your treatment.

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

Children

Prednisolone can cause enlargement of the heart in premature babies. The doctor may need to monitor babies receiving this medicine.

Other medicines and prednisolone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because prednisolone and other medicines can affect the way each other work.

In particular, check with your doctor if you are taking any of the following medicines. Your doctor may want to change the dose of prednisolone, or the other medicine.

- Painkillers such as aspirin
- Aminoglutethimide - used for some types of cancer
- Medicines for thinning your blood (such as warfarin)
- Medicines for diabetes
- Medicines for epilepsy such as phenytoin or carbamazepine
- Medicines for tuberculosis (TB) e.g. isoniazid
- Medicines which contain oestrogens including oral contraceptives
- Certain antibiotics such as clarithromycin, telithromycin, erythromycin, rifampicin, rifabutin
- Barbiturates, used as a sedative or

anticonvulsant, such as phenobarbital or primidone

Some medicines may increase the effects of prednisolone and your doctor may wish to monitor you carefully if you are taking these medicines:

- some medicines for HIV such as ritonavir, cobicistat
- some diuretics
- a medicine called carbenoxolone which is used to treat inflammation/ulceration of the stomach or gut

Vaccinations

If you have just had any injections or vaccinations, tell your doctor before you take prednisolone. If you are going to have any injections or vaccinations, tell your doctor or nurse you are taking prednisolone. This includes those needed for a foreign holiday. Some vaccines should not be given to patients taking prednisolone. This is because prednisolone can affect the way some vaccines work.

Operations

If you are going to have an operation, tell your doctor or nurse you are taking prednisolone. Muscle relaxants are sometimes used during an operation or in an intensive care unit. These and prednisolone can affect one another.

Pregnancy and breast-feeding

Talk to your doctor before taking prednisolone if:

- You are pregnant, plan to get pregnant, or think you may be pregnant
- You are breast-feeding, or planning to breast-feed

Prednisolone and infections

Taking Prednisolone can mean that you get infections more easily than usual, and these infections can be more serious.

Chicken pox or shingles

If you get chickenpox or shingles while taking prednisolone, you can become seriously ill.

- **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**.

- If you do come into contact with someone with these infections, you must see your doctor or pharmacist straightaway. Your doctor may want to give you a vaccination to help stop you from getting these infections.
- If you do catch chicken pox or shingles, tell your doctor straightaway. Your doctor will advise you on how to take prednisolone. You may be told to increase the number of tablets that you take.

Blue steroid card

- If you take this medicine for more than three weeks, you will be given a blue 'steroid card' by your doctor or pharmacist
- It contains information about your medicine, including dose instructions. This is important if you were to fall ill or be involved in an accident
- You should carry the card with you at all times

Prednisolone contains lactose

This medicine contains lactose. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE PREDNISOLONE

Always take this medicine exactly as your doctor has told you. The dose will depend on the illness being treated and any other medicines you are taking. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow your tablets whole with a glass of water
- It is important to take your medicine at the right times

Usual doses

- The usual starting dose is 3 tablets, taken together each morning
- Your doctor may decide that you need more

tablets than this each day

- Your doctor may tell you to take the medicine every other morning
- Your doctor may change your dose if you have been taking prednisolone for a long time, if you become ill or need to have an operation

Always follow your doctor's advice about how and when to take your medicine and always read the label on the pack. If you are not sure, ask your doctor or pharmacist.

If you take more Prednisolone than you should

Tell your doctor or go to the nearest hospital casualty department straight away. Remember to take with you any tablets that are left and the pack. This is so the doctor knows what you have taken.

If you forget to take Prednisolone

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

Stopping treatment

- You need to take Prednisolone regularly to get the maximum benefit.
- Don't stop taking this medicine without talking to your doctor - you may need to lower the dose gradually.
- Stopping the treatment suddenly can sometimes cause problems such as a high temperature, a runny nose, sore, red, sticky eyes, aching muscles and joints, itchy skin and weight loss. Also, sickness (vomiting), headaches and drowsiness – this is more likely to happen in children

You may also notice the following symptoms if you stop treatment with prednisolone. If this happens, tell a doctor straightaway as these could be signs of a serious illness:

- Sudden, severe pain in the back, stomach and legs
- Being sick (vomiting) and diarrhoea
- Feeling faint or dizzy, this could be a sign of low blood pressure

4. POSSIBLE SIDE EFFECTS

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

Stop taking your medicine and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria).
This may mean you are having an **allergic reaction** to Prednisolone 25mg Tablets
- You pass black tarry stools or notice fresh or clotted blood in your stools (faeces). You may also notice dark bits that look like coffee grounds in your vomit. These could be signs of a stomach ulcer
- You get severe stomach pain which may reach through to your back. This could be a sign of pancreatitis

Serious effects: Tell a doctor straight away if you notice any of the following side effects:

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. These side effects include:

- 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

Other serious side effects include:

- A very sore throat. You may also have difficulty in swallowing and the inside of your mouth may have white areas on the surface
- Headache, which is usually worse in the



morning, on coughing or straining, and feeling sick (nausea). Also, fits, fainting, eyesight problems, painful eyes, distortion/ loss of vision or confusion can occur

- 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)

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

Other side effects:

If any of these side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

- Slow heart rate (frequency not known)
- Stomach or bowel problems such as feeling full or bloated, indigestion, heartburn or stomach pain
- Increase in appetite and weight gain including developing a rounder face. Or, you may lose weight or feel weak.
- Bones and tendons may break or tear more easily than usual (called 'osteoporosis')
- Irregular periods in women or they may stop altogether
- Hair, including body or facial hair, grows more than normal
- Increased thirst and needing to pass water more often than usual. These could be signs of diabetes. If you are already diabetic, your doctor may prescribe more of your diabetes medicine to balance the effect of prednisolone. You should discuss this with your doctor
- Raised blood pressure and increased water retention
- Tiredness, confusion, muscle weakness and muscle cramps. This may be due to low levels of potassium in your body
- Mood changes, restlessness, difficulty in sleeping
- Becoming dependent on prednisolone (also called psychological dependence)
- If you have epilepsy you may notice you get

fits (seizures) more often than usual or they are more severe. If this happens, tell your doctor as he/she may want to change the dose of your epilepsy medicine while you are taking prednisolone

- If you have schizophrenia your symptoms may get worse
- If you have had tuberculosis (TB) in the past it may return
- Eye problems such as glaucoma and cataracts can happen if you take this medicine for a long time
- Blurred vision
- Eye infections (fungal or viral) may spread or return if you have had them in the past
- Increase in the risk of clots forming in your blood
- Blood problems such as leukocytosis
- Wounds and cuts do not heal as quickly as usual
- Skin problems such as bruising, red or purple discoloured spots on the skin (purpura), acne, flushing, redness, thinning of the skin and appearance of stretch marks
- General muscle weakness or tiredness
- You may get infections more easily than usual
- Sudden or severe muscle weakness or tiredness following an operation or time spent as a patient in an Intensive Care Unit (see section 2 above on 'Operations')

Some of the above effects are more likely to happen if you are elderly

Prednisolone can cause enlargement of the heart in premature babies.

Children and teenagers taking this medicine may grow less than normal. If you think this is happening to a child, tell your doctor.

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: 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

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more information on the safety of this medicine.

5. HOW TO STORE PREDNISOLONE

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton and on the blister after EXP.
- Keep this medicine below 25°C, in a dry place and protect it from light. Keep it in the pack in which it was given to you. Do not transfer your medicine to another container.
- 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 25mg Tablets contain:

- Each tablet contains 25mg of the active ingredient, prednisolone.
- Other ingredients are: lactose, potato starch, pregelatinised maize starch, magnesium stearate and purified talc.

What Prednisolone 25mg Tablets look like and contents of the pack:

Prednisolone 25mg tablets are white, round, bevel edged tablets with a break line on one side and plain on the other.

This medicine comes in blister packs of 56 tablets.

The Marketing Authorisation Holder is:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

The Manufacturer is:

Opella Healthcare International SAS, 56 Route de Choisy, 60200 Compiègne, France.

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