

## PACKAGE LEAFLET: INFORMATION FOR THE USER Prednisolone 1mg and 5mg Tablets

(Referred to as Prednisolone Tablets in the remainder of the leaflet)

### Prednisolone Leaflet - Headlines

- **Prednisolone is a steroid medicine**, prescribed for many different conditions, including serious illnesses
- You need to take it regularly to get the maximum benefit
- Do not 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 for more information). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems may be experienced straight away. If you feel unwell in any way, keep taking your tablets, but see your doctor straight away
- Some side effects only occur 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 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.

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.

You should keep this leaflet throughout your course of treatment.

**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 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 or 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 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 Tablets.

The active ingredient in your medicine is prednisolone. Prednisolone belongs to a group of medicines called steroids. Their full name is corticosteroids.

These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroids (such as Prednisolone Tablets) 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.

### 2. What you need to know before you take 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)
- have any infection, unless you are receiving specific treatment for it
- are suffering from a herpes infection of the eye
- are suffering from galactose or lactose intolerance or glucose-galactose malabsorption.

#### Warnings and precautions

**Talk to your doctor or pharmacist or nurse before taking Prednisolone Tablets if:**

- **you have ever had severe depression** or manic-depression (bipolar disorder). **This includes having had depression before whilst taking steroid medicines like prednisolone**
- **any of your close family** has had these illnesses.

If any of these apply to you, **talk to your doctor before taking Prednisolone Tablets.**

**Also talk to your doctor before taking Prednisolone Tablets if you have:**

- osteoporosis (weakening of the bones) especially in women who have passed menopause
- high blood pressure or heart failure
- diabetes or a history of diabetes in your family
- tuberculosis (a disease of the lungs) or a history of tuberculosis
- glaucoma (a condition of the eye that affects the vision) or a history of glaucoma or a history of glaucoma in your family
- a history of muscle weakness caused by treatment with steroids
- severe liver or kidney problems
- suffered from epilepsy, fits/seizures
- stomach ulcers
- an under active thyroid gland which can cause tiredness and weight gain
- suffered a recent heart attack,
- have ever had blood clots, (for examples, 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)

- have Duchenne's muscular dystrophy
- have inflammatory bowel disease such as Crohn's disease
- are undergoing immunosuppression therapy for example in the treatment of cancer
- 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.

#### Children and adolescents

Talk to your doctor before giving this medicine to babies, children or adolescents as it may slow their growth.

**Treatment of the elderly:** If you are an elderly patient speak to your doctor before taking Prednisolone Tablets. You may need to be supervised closely to avoid any life threatening reactions as you may have an increased risk of infections, weakening of the bones, high blood pressure, diabetes, increased potassium levels in your blood or thinning of your skin.

**Chickenpox and Shingles:** If you come into contact with chicken pox or shingles within 3 months of taking Prednisolone contact your doctor immediately.

**Measles:** Keep away from people who have measles. If you do come into contact with measles, **see your doctor immediately.**

#### Mental health problems while taking Prednisolone Tablets

Mental health problems can occur while taking this medicine (read section 4. Possible side effects for more information)

- these mental health problems can be serious
- these problems are usually experienced within a few days or weeks of starting the medicine
- these problems are more likely to happen at high doses
- most of these problems go away if the dose is lowered of the medicine is stopped. However, if mental health problems do occur they might need treatment.

Talk to your 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 been experienced when doses are being lowered or stopped.

#### Other medicines and Prednisolone Tablets

Please tell your doctor or pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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). The following medicines can affect or can be affected by Prednisolone Tablets:

- antiepileptic drugs such as phenobarbital, carbamazepine, phenytoin, primidone and phenobarbitone, used to treat fits/seizures or epilepsy
- antivirals such as ritonavir which can be used to treat HIV infection
- antibiotics such as erythromycin, rifampicin and rifabutin, which are used to treat some bacterial infections
- thalidomine and aminoglutethimide, used to treat some cancers
- coumarin anticoagulants for example warfarin, which is used to thin the blood
- aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) for example ibuprofen and indometacin, used to treat pain and inflammation due to increased risk of bleeding in the gut or ulcers
- somatropin or growth hormones
- isoniazid, used to treat tuberculosis
- antifungals such as ketoconazole and amphotericin, which are used to treat fungal infections
- ciclosporin, which is used to treat rheumatic disease, skin complaints, inflammation, or after a transplant
- ritonavir and indinavir, used to treat viral infections
- live vaccines
- medicines used to relax muscles during surgery
- cardiac glycosides for example digoxin and related drugs called cardiac glycosides, used to treat heart failure or help strength a weak heart
- salbutamol, formoterol, fenoterol, ritodrine, bambuterol, salmeterol and terbutaline or other sympathomimetic drugs, used to treat breathing difficulties (asthma)
- insulin and other medicines used to treat diabetes
- medicines used to treat high blood pressure
- theophylline, used to treat asthma and chronic obstructive pulmonary disease (COPD)
- loop diuretics for example furosemide which is used to treat heart failure and thiazide diuretics for example bendroflumethiazide, used to remove excess water from the body or high blood pressure
- female sex hormones - oestrogens, for example in the oral contraceptive pill or HRT
- mifepristone, used to induce labour or abortion
- cytotoxic drugs for example methotrexate which is used to treat cancer
- vaccinations: You must tell your doctor or nurse that you are taking a steroid before you are given any vaccinations. Steroids affect your immune response and you must not be given any live vaccines
- carbenoxolone which is used for ulcers
- antimuscarinics/anticholinergics
- immunosuppressants which dampen down the activity of the body's immune system
- antacids such as magnesium trisilicate or aluminium hydroxide, used to treat the symptoms of heartburn and indigestion
- acetazolamide which is used in the treatment of glaucoma and epilepsy
- antithyroids such as carbimazole.

Prednisolone Tablets may also reduce the effectiveness of the contraceptive coil (IUD or intra-uterine device) in preventing pregnancy.

If you have any doubts about whether you should take this medicine, talk to your doctor.

#### **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. Your doctor will decide if you should take them.

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

#### **Driving and using machines**

If you feel dizzy or tired after taking prednisolone 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.

### **3. How to take Prednisolone 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.

#### **You need to take Prednisolone Tablets regularly to get the maximum benefit.**

Swallow Prednisolone Tablets whole (do not chew) with water. Take your tablets with or after food.

#### **Adults and Elderly**

Your doctor may start your treatment with the lowest dose for a minimum period of time to minimise side effects.

Your doctor may decide to start your treatment with Prednisolone Tablets at a dose of 5mg to 60mg taken daily either in several doses throughout the day, or as a single dose in the morning after breakfast, or as a double dose on alternate days. The dose may be lowered after a few days to 2.5mg to 15mg per day, but your doctor may decide higher doses may be needed for several weeks or months.

#### **Use in children**

Prednisolone Tablets may be given to children very rarely to treat specific conditions. The smallest dose may be given for the shortest time possible.

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

Tell your doctor or go to your nearest hospital straight away. Take any Prednisolone Tablets that are left and this leaflet with you.

#### **If you forget to take Prednisolone Tablets**

If you forget a dose, take it as soon as you remember. However, if it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Prednisolone Tablets**

**Do not stop taking this medicine without talking to your doctor** – you may need to reduce the dose gradually.

Your doctor will decide how to lower the dose gradually depending on how long you have been taking Prednisolone Tablets, how you are responding to the treatment, your normal dose and what you are being treated for.

If treatment is stopped too quickly it can lead to severe problems of the adrenal gland. You may also experience 'withdrawal symptoms' which include fever, muscular pain, weakness, joint pain, runny nose, an eye infection (conjunctivitis), painful itchy skin lumps, loss of weight, mental changes, mood changes, feeling sick and/or being sick, low blood pressure, feeling faint, headache, dizziness and reappearance of your disease symptoms.

Children may also experience swelling of the nerves in the eyes due to increase in pressure in and around the brain. Fits/seizures may also be aggravated.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

### **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.

**If you experience any severe allergic reaction, contact your doctor or nearest hospital casualty department immediately.**

**If you experience any serious side effects tell your 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 Tablets.

If you notice any of these problems **talk to your doctor straight away:**

- 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, or 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 side effects that may be experienced while taking this medicine are:

- tiredness
- increased number of white blood cells
- blood clotting
- nausea and vomiting
- heart problems which can cause shortness of breath
- convulsions
- dizziness
- vertigo
- headache
- raised pressure in the brain (which can cause headaches, nausea and vomiting)
- sleeplessness

- thinning of the skin
- bruising
- stretch marks
- patches of skin reddening
- itching
- rash
- hives
- acne
- extra hair growth
- slow healing of wounds
- increased sweating
- 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
- face becomes very round
- weight gain
- increased blood sugar
- carbohydrate imbalance in diabetes
- euphoria (feeling high)
- feeling of dependency on treatment
- depression
- general unwell feeling
- vision problems
- worsening of schizophrenia
- worsening of epilepsy
- risk of stroke is increased in Horton disease
- increased pressure in the eyeball (glaucoma)
- whitening 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
- 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
- brittle bone disease or wasting of the bones
- bone fractures
- tendon rupture
- 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.

#### **Side effects where the frequency is not known:**

- 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.
- Slow heart rate.

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 national reporting system listed below:

United Kingdom:

Yellow Card Scheme

Website: [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.

- do not store above 25°C
- do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of the month.

Do not throw away 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 is prednisolone.

Each Prednisolone 1mg Tablet contains 1mg of prednisolone. Each Prednisolone 5mg Tablets contains 5mg of prednisolone.

The other ingredients are lactose, maize starch, stearic acid, purified talc and magnesium stearate.

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

Prednisolone 1mg Tablets are white circular, flat-faced tablets with a break line and marked CP on one side and PL1 on the other side.

Prednisolone 5mg Tablets are white circular, flat-faced tablets with a break line and marked CP on one side and PL5 on the other side.

Both strengths of tablet are available in 1000 tablet containers or 28 tablet blister packs.

#### **Marketing Authorisation Holder:**

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

#### **Manufacturer:**

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

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