

## Package leaflet: Information for the user

### PREDNISOLONE 5mg TABLETS

#### Prednisolone

- **Prednisolone is a steroid medicine**, prescribed for many different conditions, including serious illness.
- **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 'Possible side effects' 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 it for more than 3 weeks, you will get a 'steroid treatment 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 further questions, please 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, 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 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**

Prednisolone belongs to a group of medicines called steroids. Their full name is corticosteroids. 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 reduces the inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Prednisolone is used in a wide range of inflammatory and auto-immune conditions including:

- Severe allergic reactions (anaphylactic reactions) with the following symptoms:
  - breathing difficulties
  - drop in blood pressure, possibly leading to collapse which is potentially life threatening

- Allergies (hypersensitivity):
  - asthma
  - reactions to drugs
  - serum sickness (an allergic reaction to the injection of antiserum containing antibodies against a specific disease. Symptoms include hives, swelling, arthritis and fever)
- Inflammation affecting the:
  - blood vessels and heart
  - bowel or kidneys
  - muscles and joints, including rheumatoid arthritis
  - lungs, including asthma
  - eye or nervous system
- Some cancers, including leukaemia, lymphoma and myeloma
- To boost steroid levels of cortisone when the body is not making enough natural steroid on its own to maintain good health
- High levels of calcium caused by:
  - Sarcoidosis (a disease of unknown cause that leads to inflammation and can affect various organs in the body)
  - vitamin D excess
- Some infections
- Some skin conditions
- To prevent organ rejection after a transplant
- Hyperpyrexia (an extremely high temperature that sometimes occurs in infectious diseases especially in young children).

## 2. Before you take Prednisolone

### Do not take Prednisolone

- if you are **allergic** to prednisolone or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- if you have **cold sores** (herpes infection) that affect the **eyes**
- if you have ever suffered from a **stomach ulcer**
- if you have an **untreated infection**. While you are taking steroids, you are more likely to develop illnesses due to infection. Also any existing infections may become worse resulting in septicaemia (blood poisoning). This is especially so during periods of stress. Certain infections can be serious if not controlled.

### Check with your doctor first

- **If you have ever had severe depression or manic-depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Prednisolone.
- **If any of your close family** has had these illnesses.
- **If you have or ever had mental health problems** such as a rapid change of mood or emotional state (emotional instability) or psychoses, as Prednisolone may aggravate them.

If either of these applies to you, **talk to a doctor before taking Prednisolone.**

### Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolone

Tell your doctor of any medical problems you may have, or have previously had, especially

- if you suffer from, or you have ever been treated for **tuberculosis (TB)**
- if you have just had a **vaccine** or are **planning to have a vaccination**
- if you have **heart, kidney or liver disease**
- if you have suffered **congestive heart failure**
- if you have **high blood pressure**

- if you suffer from or have a family history of **diabetes**
- if you have **osteoporosis (brittle bones)**
- if you suffer from **epilepsy (fits)**
- if you have taken Prednisolone (or other steroids) before and had **muscular problems (steroid myopathy)**
- if you are receiving treatment for a condition called **myasthenia gravis (a rare muscle weakness disorder)**
- if you have ever had **blood clots** (for example, **deep vein thrombosis [DVT]**, or **thromboembolism**)
- if you 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)
- if you suffer from **hypothyroidism** (an underactive thyroid gland which can cause tiredness or weight gain)
- if you have or **have been in contact with anyone who has chickenpox, shingles or measles. Contact your doctor immediately for advice. It is also important that you contact your doctor if you contract chickenpox, shingles or measles within a 3 month period after stopping treatment**
- if you have **glaucoma** (painful eyes with blurred vision) or a **family history of glaucoma.**
- if you have **Scleroderma** (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15mg 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.

### **Elderly people**

If you are elderly your doctor will prescribe the lowest dose required since side effects can be more serious in the elderly.

### **Children and Adolescents**

Corticosteroids can slow down growth in infants, children and adolescents and this effect may be irreversible.

### **Steroid Treatment Card**

Patients taking steroids should be given a 'STEROID TREATMENT CARD' by their doctor. You should keep this card with you always and you should show it to any doctor, dentist, nurse, midwife or anyone who is giving you treatment.

Your doctor will prescribe you with the lowest effective dose for the minimum period in order to minimise the risk of developing side effects (see Section 4 Possible side effects).

### **Other medicines and Prednisolone**

Tell your doctor or pharmacist 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 and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

**It is especially important for your doctor to know if you are already being treated with any of the following medicines:**

- Medicines to treat **epilepsy (fits)** such as **carbamazepine, phenytoin, primidone** and **phenobarbital**
- Antibiotics used to treat **bacterial infections** such as **tuberculosis (e.g. rifampicin)**
- Medicines used to treat **breast cancer (e.g. aminoglutethimide which is a steroid inhibitor)**
- **Cytotoxic drugs (e.g. methotrexate)** which is used to treat **cancer**
- Medicines for **diabetes** including **insulin**

- Drugs used to **lower blood pressure**
- **Diuretics**, which are used to increase the flow of urine such as **furosemide**
- **Acetazolamide**, a drug used to treat **glaucoma** and **epilepsy**
- **Carbenoxolone**, which is used to treat **stomach ulcers**
- **Anticoagulants** - medicines used to thin the blood (e.g. **warfarin**)
- **Aspirin** and other **non-steroidal anti-inflammatory drugs (NSAIDs)**, used to control **pain** and **inflammation**, such as **indometacin**
- **Oestrogens** for example in the **contraceptive pill** or **HRT**
- Some **antibiotics** (e.g. **erythromycin** and **rifamycin**)
- **Antifungals** such as **ketconazole** and **amphotericin**, which are used to treat **fungal infections**
- **Antiviral** drugs such as **ritonavir** and **indinavir**
- **Cardiac glycosides** such as **digoxin** which is used to **strengthen a weak heart**
- Drugs used to treat **myasthenia gravis** (a type of muscle weakness)
- **Ciclosporin** (used to **control inflammation**) to treat **rheumatic disease**, **skin complaints** or **following an organ transplant**
- **Somatropin**, which is a **growth hormone**
- Drugs used to treat **asthma** such as **salbutamol**, **formoterol**, **bambuterol**, **fenoterol**, **ritodrine**, **salmeterol** and **terbutaline**
- **Mifepristone**, used to **induce labour** or **terminate pregnancy**
- **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.
- **Theophylline** which is used for **asthma** and **chronic obstructive pulmonary disease (COPD)**
- **Rifabutin** a medicine used to treat infections such as **tuberculosis**

### **Pregnancy and breast-feeding**

If you are pregnant or trying to become pregnant, you must tell your doctor before you start the treatment. If you are breast-feeding you must tell your doctor before you start the treatment. Your doctor will want to examine your baby during your time of treatment. Small amounts of steroids are present in breast milk.

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

### **Driving and using machines**

The effects of Prednisolone on the ability to drive and operate machinery has not been studied.

However, there is no evidence to suggest that Prednisolone is likely to affect your ability to drive or to operate machinery.

### **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**

**You will be supplied with a 'STEROID TREATMENT CARD' which includes important details of your treatment. This card should be carried at all times.**

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

The tablets should be swallowed with water.

### Adults

The dose may vary from 5 – 60 mg daily depending on the condition being treated. In some instances, the dose may only be taken every other day. Once your condition starts to get better, your doctor may change your dosage to a lower one. Your doctor may also reduce your dosage before stopping treatment completely.

### Children and Adolescents

If this medicine is prescribed for a child make sure the tablets are taken as stated on the label. The use of steroids can slow down normal growth of children and adolescents. In order to lessen this effect the tablets are often taken in a single dose every other day.

### **Mental problems while taking Prednisolone**

Mental health problems can happen while taking steroids like Prednisolone (see also section 4 Possible Side Effects).

- 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), shows 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.

### **Route of administration**

The score line is only there to help you to break the tablet if you have difficulty swallowing it whole.

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

If you have taken too many tablets you should contact your nearest hospital casualty department or your doctor immediately.

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

If you forget to take a dose take the next dose as soon as you remember, then go on as before. Never take two doses at the same time.

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

DO NOT suddenly stop taking your tablets unless advised by your doctor as you may experience the following symptoms: fever, painful muscles and joints, inflammation of the eyes and nasal passages, painful and itchy skin lumps and loss of weight.

Withdrawal of treatment in the following patients should be gradual;

- If you have been taking corticosteroids for a long time
- If you have stopped taking a long term dose of corticosteroids less than one year ago and your doctor has recently prescribed you with a short course
- If you have been taking Prednisolone because your body can not produce enough steroids
- If you have been taking more than 40 mg Prednisolone (or equivalent) daily
- If you have been taking doses repeatedly in the evening.

If the dose is reduced too quickly, patients can suffer from suppression of the adrenal gland, low blood pressure and even death.

If you have any further questions on the use of this product, ask your doctor.

## **4. Possible side effects**

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

**Serious side effects: tell a doctor straight away**

**Tell a doctor immediately if you experience any of the following symptoms:**

- 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.
  - **Feeling depressed, including thinking about suicide**
  - **Feeling high (mania) or moods that go up and down**
  - **Irritable, 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.**

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

- **Severe sudden allergic reaction with the following symptoms:**
  - **Rash**
  - **Itching**
  - **Difficulties in breathing or swallowing**
  - **Swelling of the face, lips, tongue or throat**
- **Inflammation of the pancreas (very severe abdominal pains)**
- Prednisolone can irritate the stomach causing indigestion and even ulcers. **Tell your doctor immediately if you get indigestion or stomach pains, vomit blood or what looks like coffee grounds, or pass black or mahogany-coloured stools (faeces).**

Prednisolone can slow growth in babies, children and adolescents.

#### **Other possible side effects**

- **Stomach and Intestines** - increased appetite which may result in weight gain, indigestion, a feeling of being full or bloated, very sore throat and white areas inside your mouth (oral thrush), abdominal pain, diarrhoea, nausea, stomach ulcers, or ulcer in your gullet (oesophagus)
- **Heart and blood vessels** - high blood pressure, heart failure in patients who are at risk, frequency not known: Slow heart rate
- **Central and Peripheral Nervous system** - convulsions, dizziness, headache, increased intracranial pressure usually after treatment.
- **Muscle or bones** - muscle weakness or wasting, pain in back, hips, ribs, arms, shoulders or legs. Osteoporosis (may be easier to fracture your bones or to tear your tendons), tendon rupture
- **Kidney** - water and salt retention, cramps and spasms due to potassium loss in your body
- **Skin** - reduced skin healing, thinning of the skin, bruising, stretch marks, patches of reddening, itching, rash, hives and acne. Extra hair growth, increased sweating, may suppress reactions to skin tests
- **Hormones** – filling or rounding out of the face, periods become irregular or stop altogether, unusual increase in hair growth on body or face. Growth in babies, children and adolescents may be reduced. Weight gain, carbohydrate imbalance in diabetes, increased appetite, diabetes, weight loss, loss of appetite, reduction in the level of protein and calcium in the blood, absence or irregularity of menstrual periods.

Prednisolone may suppress the production of natural corticosteroids in your body. This will depend on your dose, how often you are taking Prednisolone, when you are taking it and how long you are taking Prednisolone. This is more likely to happen during times of stress, such as trauma, surgery or illness. If you are on long term therapy and you experience any of these events, your doctor may increase your dose of Prednisolone.

- **Nervous disorders** - euphoria (feeling high), feeling of dependency on treatment, depression, sleeplessness, pressure on the nerve of the eye (sometimes in children after stopping treatment) causing painful eyes, changes in vision or a bad headache, especially behind your eyes, worsening of schizophrenia, worsening of epilepsy, spinning sensation (vertigo), raised head pressure due to swelling of a nerve in the eye (papilloedema) in children

- **Eyes** - increased pressure in the eyeball (glaucoma), whitening or clouding of the lens (cataracts), pressure on the nerve to the eye, thinning of the tissues in the eye (sclera or cornea), worsening of viral or fungal infections of the eye
- **Blurred vision:** rare (may affect up to 1 in 1,000 people)
- **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.
- **Infections** – lowered resistance to infections, such as cold, existing eye infections may become worse or symptoms of a previous infection such as tuberculosis (TB) can reappear. This is especially important regarding chickenpox or measles.
- **General** - increased number of white blood cells, blood clotting, allergy, thrombosis, nausea and vomiting, tiredness, feeling poorly (malaise).
- **Withdrawal symptoms** - muscle or joint pain, conjunctivitis, fever, weight loss, runny nose and painful, itchy skin lumps, nausea, vomiting, loss of appetite, diabetes (hypoglycaemia), feeling tired or sluggish, headache, skin peeling, low blood pressure.

### **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 national reporting system:

HPRRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine

It is important that you stay under the close supervision of your doctor. If you attend a doctor after you have stopped taking prednisolone you should let your doctor know that you have been on steroid treatment.

### **5. How to store Prednisolone**

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. Store in the original package in order to protect from moisture. Keep the blister in the outer 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 contains**

The active substance is prednisolone. Each tablet contains 5 mg prednisolone.

The other ingredients are lactose monohydrate, potato starch, colloidal anhydrous silica, sodium starch glycolate (type A), magnesium stearate.

#### **What Prednisolone looks like and contents of the pack**

5 mg tablet: White round tablet with cross-shaped breaking notch and imprint “5” on one side.

Pack size: 28, 30, 56, 60, 98, 100, 140 and 150 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

**Manufacturer**

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