

## Soluble Prednisolone Tablets 5 mg (prednisolone sodium phosphate)

Your medicine is called Soluble Prednisolone Tablets 5 mg but will be referred to as Soluble Prednisolone Tablets throughout this leaflet.

**Read all of this leaflet carefully before you start taking this medicine. It provides a summary of the information available on your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.**

- **Prednisolone is a steroid medicine**, 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 reduce the dose gradually.
- **Prednisolone can cause side effects in some people** (read section 4 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 this medicine 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 may be especially important for you.

### **Prednisolone - benefit information.**

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 corticosteroid (such as prednisolone) 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.

### **In this leaflet:**

1. What Soluble Prednisolone Tablets are and what they are used for
2. Before you take Soluble Prednisolone Tablets
3. How to take Soluble Prednisolone Tablets
4. Possible side effects
5. How to store Soluble Prednisolone Tablets
6. Further information

### **1. WHAT SOLUBLE PREDNISOLONE TABLETS ARE AND WHAT THEY ARE USED FOR**

The name of your medicine is Soluble Prednisolone Tablets. Soluble Prednisolone Tablets contain the active ingredient prednisolone which belongs to a group of medicines called corticosteroids or "steroids". Steroids work by reducing inflammation and lowering the body's immune response.

Soluble Prednisolone Tablets are used to treat a variety of inflammatory diseases including severe asthma, rheumatoid arthritis, allergic reactions, bowel diseases, severe skin conditions, kidney disorders and some blood disorders.

### **2. BEFORE YOU TAKE SOLUBLE PREDNISOLONE TABLETS**

#### **Do not take this medicine if you:**

- are **allergic** to prednisolone or any of the other ingredients of Soluble Prednisolone Tablets (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- have recently had a **vaccination** or have a vaccination planned;
- have a viral **infection** such as **measles, chickenpox or shingles**, or any other infection. Tell your doctor **immediately** if you have come into contact with anyone suffering with measles, chickenpox or shingles in the last three months.

#### **Take special care if you:**

- have or have ever had:
  - **severe depression** or manic-depressive illness (bipolar disorder). This includes having had depression before while taking steroid medicines like Soluble Prednisolone Tablets or if anyone in your family has suffered from these illnesses;
  - TB (tuberculosis);
  - diabetes;
  - epilepsy;
  - depression or other mental illness;
  - an eye disease caused by a rise of pressure within the eye (glaucoma);
  - osteoporosis (thinning of the bones);
  - muscle problems when steroids have been taken before;
  - stomach ulcers;
  - high blood pressure, heart failure or recently suffered a heart attack;
  - any liver or kidney problems;
  - an under-active thyroid (hypothyroidism).

**If any of the above applies to you, or you are not sure please tell your doctor or pharmacist before you use this medicine.**

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

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

- These illnesses can be severe.
- 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 occur 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 the medicine stopped altogether.

#### **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This is especially important if you are taking:

- Medicines for **epilepsy** such as carbamazepine, phenobarbitone, phenytoin or primidone;
- **Antibiotics** such as rifampicin, erythromycin;
- Mifepristone (used to terminate pregnancy);
- Ritonavir (used in HIV treatment);
- **Oral contraceptives**;
- Somatropin (used to treat growth problems);
- Medicines for **diabetes** such as insulin, glibenclamide or metformin;
- Medicines to treat **high blood pressure**, such as diuretics (water tablets) like bendroflumethiazide and furosemide;
- **Warfarin** or other medicines used to thin the blood;
- **Aspirin** or similar medicines;
- **Theophylline** (used to treat asthma);
- Medicines to treat **fungal infections** such as amphotericin, ketoconazole;
- Acetazolamide (used to treat glaucoma);
- Carbenoxolone (used to treat stomach ulcers);
- **Methotrexate** (used for rheumatoid arthritis, psoriasis and certain types of cancer);
- Any medicine which belong to a group of medicines called sympathomimetics;
- Medicines used to treat myasthenia gravis;
- Medicines used to make x-rays clearer;
- Ciclosporin (used to stop the body rejecting bone marrow or organ transplants).

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

Tell your doctor before being given this medicine if you are or think you may be pregnant, or if you are breast-feeding.

#### **Driving and using machinery**

This medicine should not affect your ability to drive or use machines.

#### **Carrying a Steroid card**

Your doctor or pharmacist will have given you a **Steroid Treatment Card** with your prescription or medicine. YOU SHOULD ALWAYS CARRY THIS CARD WITH YOU as it must be shown to any of the following persons:

- Doctor or Nurse** - before having any surgery or emergency treatment or if any new treatment is prescribed.

- Dentist** - before having any dental surgery.
- Pharmacist** - before buying any medicine.
- Optician** - it is advisable to have regular eye tests.

### 3. HOW TO TAKE SOLUBLE PREDNISOLONE TABLETS

Always take Soluble Prednisolone Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets can be swallowed whole, but they are **best taken as a drink** after dissolving them in a glass of water. Take your tablets as a single dose each morning, unless your doctor has told you otherwise.

#### Adults:

The dose will depend on the condition you are being treated for and can vary between 10mg and 100mg daily. Your doctor will always reduce the dose to the smallest dose that works for you.

#### Children:

To treat asthma attacks:

Children aged 5 years and above – 30 mg to 40 mg

Children aged 2 to 5 years old - 20 mg daily

Children under 2 years old – up to 10 mg daily for up to three days

Treatment for up to three days is usually enough, but may be longer.

**Do not stop** taking the tablets unless you have been told to do so by your doctor, even if you feel better, as it can make you ill. It can cause withdrawal symptoms such as fever, sickness, pain in the muscles and joints, runny nose, sore, red and sticky eyes (conjunctivitis), itchy skin and weight loss.

**Talk to your doctor** if you want to stop taking the tablets – your doctor may want to reduce your dose gradually.

#### If you take more tablets than you should

If you take more Soluble Prednisolone Tablets than you should, contact your doctor or nearest hospital emergency department **immediately**. Remember to take this leaflet and/or the package with you to show the doctor what you have taken.

#### If you forget to take your medicine

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

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Soluble Prednisolone Tablets can cause side effects, although not everybody gets them.

Steroids including prednisolone can cause severe mental health problems.

These are common in both adults and children. They can affect about five in every 100 people taking medicines like Prednisolone.

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or having moods that go up and down.
- Feeling anxious, having problems sleeping, having 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 immediately**.

#### If you notice;

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness.

**Stop taking the tablets and tell your doctor immediately. These may be signs of an allergic reaction.**

The side effects which can occur if steroids are given in high doses for a long time are:

- generally feeling unwell;
- feeling sick (nausea);
- hiccups;
- indigestion or stomach discomfort;
- stomach ulcer (which can rupture and bleed) or ulcer in the oesophagus (gullet);
- thrush;
- inflammation of the pancreas causing abdominal pain (pancreatitis);
- muscle weakness;
- muscle pain;
- thinning of bones which makes fractures more likely (osteoporosis);
- damage to tendons;
- joint stiffness causing limited movement, pain and muscle spasms;

- fluid retention causing swelling;
- feeling dehydrated;
- high blood pressure;
- slow healing of wounds, thinning of the skin, bruising, acne, marks which look like stretch marks;
- small red, purple or blue spots found along the surface of the skin (caused by blood vessels under the skin);
- low adrenal gland function;
- slowed growth in infants, children and teenagers;
- irregular or stopped menstrual periods;
- swollen, round face (Cushingoid facies);
- excess hair growth;
- increased appetite and weight gain;
- intolerance to carbohydrates;
- mood changes, dependence, depression, difficulty sleeping, worsening of schizophrenia;
- severe headaches with blurred vision or temporary visual problems in children (usually after stopping treatment);
- worsening of epilepsy;
- raised pressure in the eyes (glaucoma), cataracts, thinning and inflammation of the cornea (part of the eye), worsening of viral or fungal eye diseases and visual impairment;
- heart attack (sudden severe chest pains);
- changes in body chemistry;
- an increase in the number of white blood cells;
- formation of blood clots;
- Long term use of high dose steroids, may lead to a weakening of the immune system, which can increase the risk of malignancy.

Kaposi's sarcoma (a type of cancer) has also been reported to occur in patients receiving corticosteroids. However, once the treatment has been stopped, this may go away.

Soluble Prednisolone Tablets can make it easier for you to pick up infections which may very rarely be fatal. Infections such as chicken-pox and measles can be made worse or TB (tuberculosis) may recur.

If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please **tell your doctor or pharmacist immediately**.

**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](http://www.mhra.gov.uk/yellowcard). By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE SOLUBLE PREDNISOLONE TABLETS

Do not store above 25°C. Store in the original package. Do not take any tablets after the "use by" date shown on the pack. Return any unused tablets to your pharmacist.

If your tablets show signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer require or medicines that have expired. These measures will help to protect the environment

### KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN

### 6. FURTHER INFORMATION

#### What Soluble Prednisolone Tablets contain

Each tablet contains 5 mg of the active ingredient prednisolone (as prednisolone sodium phosphate)

The other ingredients are: povidone, sodium acid citrate, sodium bicarbonate, sodium benzoate (E211), erythrosine (E127) and saccharin sodium.

#### What Soluble Prednisolone Tablets look like and the contents of the pack

The tablets are small, pink, circular, flat, bevel-edged soluble tablets engraved with 'PRED 5' on one side and scored on the reverse. The tablets are foil strip packed and supplied in cartons of 30 and 100.

Manufactured by:

EirGen Pharma Limited, Westside Business Park, Old Kilmeaden Road, Waterford, Ireland or:  
 Losan Pharma GmbH, Otto-Hahn-Strasse 13, D-79395 Neuenburg, Germany

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