PACKAGE LEAFLET: INFORMATION FOR THE USER

Prednisolone 5 mg Soluble Tablets

(Prednisolone sodium phosphate)

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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Prednisolone tablets 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 tablets 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 "Possible side effects" for more information).
- **If you take it for more than 3 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 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.

What is in this leaflet

1. What Prednisolone soluble tablets are and what are they used for
2. What you need to know before you take Prednisolone soluble tablets

3. How to take Prednisolone soluble tablets
4. Possible side effects
5. How to store Prednisolone soluble tablets
6. Contents of the pack and other information

1. What Prednisolone Soluble Tablets are and what they are used for

Prednisolone 5 mg Soluble Tablets (called Prednisolone Soluble Tablets throughout the rest of this leaflet) contain the active ingredient 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 corticosteroid (such as prednisolone) is an effective way to treat various illnesses involving inflammation in the body. Prednisolone Soluble Tablets reduce 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 soluble tablets are used to treat a variety of inflammatory and immunological disorders including:

- acute asthma that has not responded to inhaled steroids,
- rheumatoid arthritis,
- inflammatory conditions of the arteries,
- inflammation of the liver,
- inflammatory diseases affecting the bowel,
- pemphigus which is a rare and serious skin condition,
- kidney disorders,
- some blood disorders and serious diseases of the white blood cells.
- These tablets are used to prevent organ rejection in patients who have received an organ transplant (such as a liver or heart transplant).

Many different diseases may be improved by the careful use of effective medicines like this, which mainly work by reducing inflammation in the body. If you are not sure why you are taking these tablets, ask your doctor.

2. What you need to know before you take Prednisolone Soluble Tablets

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 soluble tablets.

- **If any of your close family** has had these illnesses.

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

• 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.

Do not take Prednisolone soluble tablets:

- If you are allergic to prednisolone or any of the other ingredients of this medicine (listed in section 6).
- If you have untreated stomach ulcers, tuberculosis (TB), or are suffering from an untreated infection
- If you are suffering from acute psychosis (you may feel, see or hear things that do not exist or have strange or frightening thoughts, which you cannot control)
- If you have received any "live injections" for immunisation.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolone soluble tablets if you have or have ever had:

- diabetes, epilepsy, depression, manic depressive illness (bipolar disorder) or other mental illness, glaucoma (raised eye pressure), heart failure or recently suffered a heart attack, hypertension (high blood pressure), osteoporosis (thinning of the bones) or stomach ulcers
- any liver or kidney problems
- muscle problems when steroids have been taken before
- a recent immunisation (vaccinated) or have a vaccination planned
- a viral infection such as measles, chickenpox or shingles, or any other infection
- been in contact or, during the last few months come into contact with anyone suffering from measles, chickenpox or shingles. If you have not had chickenpox it is important to avoid contact with the disease
- if you have stayed in tropical, subtropical or southern Europe, due to the risk of parasitic disease
- are pregnant or planning to become pregnant (see Pregnancy and Breastfeeding)
- a suppressed immune system e.g. following organ transplant
- any wounds not healing
- thinning of the skin
- if you are an athlete, since prednisolone may produce a positive result in anti-doping tests.

Or if Prednisolone Soluble tablets are prescribed:

- in children being treated for growth retardation, or
- when you already require daily treatment with steroids for another condition.

Children and adolescents

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.

Elderly

When steroids are taken by elderly patients some of the unwanted side effects can be more serious especially brittle bone disease, diabetes, high blood pressure, infections and thinning of the skin.

Other medicines and Prednisolone Soluble Tablets

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

Some medicines may increase the effects of Prednisolone Soluble Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Tell your doctor if you are taking

- medicines for epilepsy such as carbamazepine, phenobarbital, phenytoin or primidone, antibiotics such as rifampicin or rifabutin
- ephedrine (found in certain cough and cold remedies),
- warfarin (or other anticoagulants used to thin the blood),
- aminoglutethimide (which reduces natural steroids in the body),
- insulin, glibenclamide, metformin (or other treatments for diabetes),
- bendrofluazide, furosemide (used for certain heart and kidney conditions such as high blood pressure),
- non-steroidal anti-inflammatory drugs (such as ibuprofen, also called NSAIDs and used for pain relief and to treat rheumatic disease),
- oestrogens (found in the contraceptive pill or HRT),
- long term treatment with aspirin or other salicylates,
- cholecystographic X-ray media (used for gall bladder x-rays),
- ciclosporin (used to stop the body rejecting bone marrow or organ transplants),
- mifepristone (used to terminate pregnancy),
- ritonavir, cobicistat (used in HIV treatment),

- certain drugs used in treatment of asthma eg: bambuterol, fenoterol, formoterol, salbutamol, salmeterol, terbutaline and theophylline,
- any medicines which belong to a group of medicines called cardiac glycosides (such as digoxin, digitoxin and digitalis)
- isoniazid and fluoroquinolones (used to treat infections)acetazolamine (used to treat glaucoma),
- carbenoxolone (used to treat stomach ulcers),
- somatropin (used to treat growth problems),
- amphotericin (used to treat fungal infections)
- methotrexate (used for rheumatoid arthritis, psoriasis and certain types of cancer),
- medicines used to treat myasthenia gravis.

Sportsmen

Prednisolone may produce a positive result in anti-doping tests.

Pregnancy, breast-feeding and fertility

Pregnancy

You must tell your doctor if you think you are pregnant or might become pregnant. If steroids are taken for long periods of time or repeatedly during pregnancy, there may be an increased risk of the baby growing more slowly while in the mothers' womb. However there are certain clinical situations where it would be a greater risk to the mother and child to stop taking Prednisolone Soluble Tables than carrying on taking them. Your doctor will advise you.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding.

Driving and using machines

If you feel dizzy or tired after taking Prednisolone Soluble Tables do not drive or operate machinery until these effects have worn off.

Prednisolone soluble tablets contain sodium and sodium benzoate

- This medicine contains 27.9 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.4 % of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains 7.5 mg benzoate salt in each tablet. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Prednisolone Soluble Tablets

Your doctor will decide on the most appropriate dose to treat you or your child.
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Dosage depends on the condition being treated and, for an adult, can vary widely between 7.5 mg and 100 mg daily, usually taken in divided doses, always reducing to the smallest dose that works.
- If prescribed for a child, make sure the tablets are taken as the label says.
- If you are on long-term therapy make sure your supply of tablets does not run out.

Method of administration: For oral use only

- Prednisolone Soluble Tablets are best taken dissolved in a glass of water, however, they can also be taken whole, with a drink of water;
- dissolve the number of tablets, that your doctor has told you to take, in a glass of water, and then drink all of it immediately;
- do not leave your drink where someone else may drink it as your medicine could harm them;
- the tablet can be divided into equal doses.

If you take more Prednisolone Soluble Tablets than you should

If you take more tablets than your doctor has told you to, contact a doctor or your nearest hospital casualty department **immediately**. Remember to take this leaflet and/or package with you to show the doctor what you have taken.

If you forget to take Prednisolone Soluble Tablets

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 Soluble Tablets

Don't stop taking this medicine without talking to your doctor first - you may need to reduce the dose gradually. You must continue to take your medicine even if you are feeling better. Do not stop taking this medicine suddenly. Once your condition starts to get better, your doctor may change your dose to a lower one. Your doctor may also reduce your dosage to a lower one before stopping treatment completely over a number of weeks or months. If you have been taking it for three weeks or longer you should never stop taking Prednisolone Soluble Tablets suddenly and any dose reduction must be gradual. You should follow your doctor's instructions before stopping this medicine as it can make you ill. It can cause **withdrawal symptoms** which includes the following: fever, sickness, pain in the

muscles and joints, runny nose, sore, red and sticky eyes (conjunctivitis), painful itchy skin, blurred vision, low blood pressure and weight loss.

In some instances withdrawal symptoms may appear as a relapse in the condition that Prednisolone Soluble Tablets has been used to treat. In extreme cases, there may be increased pressure inside the brain which presents as headache and vomiting.

If you get severe withdrawal symptoms, tell your doctor straight away. He/she may ask you to restart taking your medicine and then to start coming off it again more slowly.

Carrying a steroid card

- if your doctor asks you to carry a **steroid card**, be sure to keep it with you always.
- Show it to any doctor, dentist, nurse or midwife, pharmacist or anyone else who is giving you treatment, medicines or vaccinations.
- Even after your treatment has finished tell any doctor, dentist, nurse or midwife, pharmacist or anyone else who is giving you treatment that you have had steroid treatment.
  A steroid card may be obtained from your doctor or pharmacist.

Mental problems while taking Prednisolone Soluble Tablets

Mental health problems can happen while taking steroids Prednisolone Soluble tablets (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 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.

4. Possible side effects

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

Severe effects: tell a doctor straight away

Steroids including Prednisolone soluble tablets 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 soluble tablets.

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or having moods that go up and down.
- Feeling anxious, feeling irritable, 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, worsening of schizophrenia

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

A few people can be allergic to some medicines after taking for a long time. If any of the following side effects come on soon after taking your tablets **tell your doctor immediately**:

- Difficulty in breathing (sudden chest tightness) or wheeziness, chest pain, heart pounding or beating irregularly,
- swelling of face, lips or throat,
- skin rash - red spots or hives (skin lumps) or itching.

Taking these tablets for a long time at a high dose or repeatedly in short courses can lead to the following side effects (where the frequency is unknown as it cannot be estimated from the available date) such as:

- slow healing of wounds, skin thinning, bruising, acne, marks which look like stretch marks,
- skin rash, skin lumps (hives) or itching, small red, purple or blue spots found at the surface of the skin (caused by blood vessels under the skin),
- excessive sweating,
- severe muscle weakness and muscle pain, aseptic osteonecrosis, particularly of the femoral head (degeneration of the bone in the hip joint),
- raised pressure in the eyes (glaucoma) cataracts, thinning and inflammation of the cornea (parts of the eye), worsening of viral or fungal eye diseases and visual impairment,
- bone thinning (osteoporosis) which makes fractures more likely particularly in post-menopausal women,
- indigestion or stomach discomfort/bloating or stomach pain,
- stomach ulcers (which can rupture and/or bleed) or ulcer in the oesophagus (gullet),
- irregular or disturbed monthly periods or absence of monthly periods,
- generally feeling unwell,
- dizziness, headaches, blurred vision or temporary visual problems, vertigo or feeling sick (nausea), vomiting, diarrhoea,
- high blood pressure,
- worsening of diabetes, and worsening of epilepsy,

- treatment with steroids can make it easier for you to pick up infections which very rarely may be fatal, infections such as chickenpox and measles, can be made worse or TB (tuberculosis) may recur,
- Cushingoid syndrome, where increased levels of naturally occurring steroids cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating with swollen, round face,
- heart attack (sudden increased chest pain), tear in the muscle of the heart wall following a heart attack, heart failure, slow heart rate,
- increased water retention causing swelling and weight gain,
- changes in the levels of some hormones, changes in body chemistry i.e. unusual levels of minerals (substances in your body which help it to work properly), electrolyte imbalance (unusual levels of salts in your body) or protein in blood tests may occur,
- increased risk of blood clotting, including venous thromboembolism,
- an increase in the number of white blood cells (leukocytosis),
- candidasis (thrush),
- hiccups,
- inflammation of the pancreas causing abdominal pain (pancreatitis),
- damage to tendons,
- joint stiffness causing limited movement, pain and muscle spasms,
- feeling dehydrated,
- low adrenal gland function or low pituitary gland function,
- excess hair growth,
- increased appetite and weight gain,
- intolerance to carbohydrates particularly in diabetics,
- 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.
- 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,
- Cases of tumor lysis syndrome have been reported in patients with blood cancer. Symptoms of tumor lysis syndrome include muscle cramps, muscle weakness, confusion, vision loss or visual disturbances, shortness of breath, convulsions, irregular heartbeat or kidney disorder (decreased amount of urine or darkening of urine). If you experience such symptoms, you should tell your doctor immediately.

If the tablets are stopped abruptly withdrawal symptoms can occur including fever, sickness, pain in the muscles and joints, runny nose, sore, red and sticky eyes (conjunctivitis), painful itchy skin and weight loss. In some instances withdrawal symptoms may appear as a relapse in the condition that Prednisolone soluble tablets has been used to treat.
In extreme cases, there may be increased pressure inside the brain which presents as headache, nausea and vomiting.

In children and adolescents, high doses taken for a long time can stunt growth and your doctor will prescribe the lowest effective dose for the shortest possible time.

If you feel unwell or have any unusual discomfort you do not understand - tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prednisolone Soluble Tablets

Keep out of the sight and reach of children.
Do not store above 30°C. Store in the original package in order to protect from light.
Do not use this medicine after the expiry date, which is stated on the package. The expiry date refers to the last day of that month.
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 Soluble Tablet contains

The active substance is prednisolone. Each soluble tablet contains 5 mg prednisolone (as sodium phosphate).

The other ingredients are sodium acid citrate, sodium bicarbonate, saccharin sodium, erythrosine, povidone K30, and sodium benzoate (E211).

What Prednisolone Soluble Tablets look like and contents of the pack

Prednisolone are pink, round, soluble tablet marked with ‘PD’ on one side and score line on the other side. The tablet size is 7.00 mm.

Prednisolone soluble tablets are available in blisters containing 20, 30 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Activase Pharmaceuticals Limited
11 Boumpoulinas, Nicosia,
1060 Cyprus

Manufacturer

Elara Pharmaservices Europe Limited
Regus Block 1, Blanchardstown Corporate Park 1,
Ballycoolen Road, Dublin 15,
D15 AKK1,
Ireland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland: Prednisolone 5 mg soluble tablets
France: PREDNISOLONE ACTIVASE 5 mg, comprimé sécable pour solution buvable

This leaflet was last revised in 02/2025