If you stop taking Prednisolone
You need to take Prednisolone regularly to get the maximum benefit. **Do not stop** taking this medicine without talking to your doctor - you may need to lower the dose gradually.

If you stop taking the tablets suddenly you may develop muscles and joints pain, conjunctivitis, a fever, weight loss, painful itchy skin lumps or runny nose.

In some severe cases a drop in blood pressure and death may occur. If you have been given Prednisolone Tablets for more than 3 weeks your doctor will ensure that your dose is gradually reduced so as to avoid any withdrawal symptoms.

It is important that you complete the course of treatment as per your doctor's instructions. Talk to your doctor before you stop taking the tablets and follow their advice.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Prednisolone can cause side effects, although not everybody gets them. Side effects mainly occur with long-term treatment, but also depend on dose size and individual sensitivity.

Contact your doctor immediately if the following serious side effects occur:
Not known (frequency cannot be estimated from the available data):
- Severe allergic reaction including angioedema. Symptoms may include: swelling of the face, tongue or throat, difficulty swallowing, hives and difficulty breathing, fever, drop in blood pressure.
- Pheochromocytoma crisis, symptoms may include: anxiety, headache, palpitations, sweating, pale skin.
- Scleroderma renal crisis may occur in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.
- Suicidal ideation (see section 2 'Warnings and precautions').

Other Side effects:
Common (may affect up to 1 in 10 people):
- Infections, the immunosuppressive effect of prednisolone may also cause infections to flare up again (e.g. tuberculosis)
- Lower concentration of certain hormones, Cushing's like appearance, growth retardation in children
- Low levels of potassium, build-up of sodium in the body, increased sugar in the blood and urine, osteoporosis
- Swelling due to fluid accumulation, high blood pressure
- Thinner skin, impaired wound healing
- Muscle wasting

Uncommon (may affect up to 1 in 100 people):
- Mental disorders (at high doses)
- Cataracts, glaucoma.
- Blurred vision

Rare (may affect up to 1 in 1,000 people):
- Depression
- Mania in patients without a history of psychiatric illness
- Benign pressure increase in the skull
- Breakdown of bone tissue, tendon rupture

Not known (frequency cannot be estimated from the available data):
- Increased number of white blood cells (leukocytosis)
- Withdrawal syndrome when reducing the dose (see section 3)
- Lowered blood pH, decreased blood potassium, elevated blood fats, impaired sugar tolerance, accumulation of fatty tissue at secluded places in the body, increased appetite (which can lead to weight gain)
- Emotional symptoms (such as elation, emotional instability, drug dependence), mental disorder (such as delusions, hallucinations and schizophrenia), personality change, confusion, anxiety, mood swings, abnormal behaviour, sleep problems, irritability
- Seizures, problems with memory, intellectual disturbance, dizziness, headache, increased amount of fat around the spinal cord
- Acid reduction (central serous chorioretinopathy), protruding eyes,
- Heart failure (in susceptible patients)
- Slow heart rate.
- Amnesia
- Blood clots
- Hiccups
- Petechiae,
- Ecchymosis
- Gastric ulcer, hole (perforation) in the gut, inflammation of the pancreas, inflammation and ulcers of the oesophagus, swollen abdomen, abdominal pain, diarrhoea, digestive problems, nausea
- Increased hairiness in women, bleeding of the skin, bruising, redness of the skin, sweating, stretch marks (blue-red patches on the chest and abdomen), itching, hives, acne
- Muscle weakness, muscle aches, bone fractures without prior trauma, joint breakdown, joint pain
- Irregular menstrual periods
- Tiredness, feeling ill
- Increased amount of calcium in the urine, elevated liver enzymes (alanine aminotransferase, aspartate aminotransferase), elevated alkaline phosphatase in the blood, elevated levels of blood urea (seen in blood tests), weaker reaction to skin tests.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any 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 more information on the safety of this medicine.

5. How to store Prednisolone

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package or container to protect from light.

Keep the container tightly closed to protect from moisture.

Do not use this medicine after the expiry date which is stated on the package or container. 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 protect the environment.

6. Contents of the pack and other Information

What Prednisolone tablets contain
The active substance (the ingredient that makes the tablets work) is Prednisolone.
The other ingredients are lactose, maize starch, pre-gelatinised starch, sodium starch glycollate and magnesium stearate.

What Prednisolone tablets look like and contents of the pack
Prednisolone 500 microgram tablets are white or creamy white, biconvex, plain tablets with 'P' engraved on one side.

Prednisolone 1 mg tablets are round, white to creamy white tablets with MP62 engraved on one side.

Prednisolone 2 mg tablets are white or creamy white, biconvex, plain tablets with 'P2' engraved on one side.

Prednisolone 3 mg tablets are white or creamy white, biconvex plain tablets with 'P3' engraved on one side.

Prednisolone 4 mg tablets are white or creamy white, biconvex plain tablets with 'P4' engraved on one side.

Prednisolone 1 mg tablets come in containers of 28, 100 and 500 tablets and in blister packs of 28 tablets.

The Prednisolone 500 microgram, 2 mg, 3 mg and 4 mg tablets come in blister packs of 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Genethics Europe Limited,
41-43 Klimentos, Klimentos Tower, Nicosia 1061, Cyprus

Manufacturer
DDSA Pharmaceuticals Limited,
84 Pembroke Road, London, W8 6NX, UK

For more information about this product, please contact the Marketing Authorisation Holder.

This leaflet was revised in 06/2024

GE0065-0036-0066-0067-0068/O/PIL/GE2

PACKAGE LEAFLET: INFORMATION FOR THE USER

PREDNISOLONE 500 microgram, 1 mg, 2 mg, 3 mg and 4 mg 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**.

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, talk to 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. Content of the pack and other information

1. What Prednisolone is and what it is used for

The name of your medicine is Prednisolone. It belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the

Package Leaflet: Information for the user
PREDNISOLONE 500 microgram, 1 mg, 2 mg, 3 mg and 4 mg TABLETS

Pharma code

Pharma code

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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.

Prednisolone can be used to treat:
Prednisolone is used in a wide range of inflammatory and auto-immune conditions including:
- allergies, including severe allergic reactions.
- inflammation affecting the:
  - lungs, including asthma
  - blood vessels and heart
  - bowel or kidneys
  - muscle and joints, including rheumatoid arthritis
  - eye or nervous system
- skin conditions.
- some infections.
- some cancers, including leukaemia, lymphoma and myeloma.
- to prevent organ rejection after a transplant.

Also:
- to boost steroid levels when the body is not making enough natural steroid on its own.
- to treat high calcium levels.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Prednisolone

Do not take Prednisolone and tell your doctor if you:
- are allergic to Prednisolone, or any of the other ingredients of this medicine (listed in section 6).
- have a fugal infection.
- have recently had any 'live' vaccinations.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you have:
- an infection or get an infection while being treated with prednisolone
- underactive thyroid gland (hypothyroidism)
- liver disease or kidney
- or have had seizures
- myasthenia gravis (a disease that causes muscle weakness
- tuberculosis or have ever been treated for tuberculosis
- or anyone in your family has diabetes
- gastric ulcer, duodenal ulcer or inflammatory bowel disease (e.g. ulcerative colitis or diverticulitis)
- diabetes
- heart disease, e.g. heart failure or high blood pressure
- had blood clots in the past (e.g., vein thrombosis) or have blood clots
- mood swings or psychotic tendencies
- any drug allergy
- osteoporosis
- adrenal tumour (phaeochromocytoma)
- new surgically created blood vessels or intestinal connections
- have scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15 mg or more of Prednisolone 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 during treatment you:
- get serious psychological side effects, e.g. depression and suicidal thoughts. These can also occur when you stop taking prednisolone.
- experience blurred vision or other visual disturbances.
- are subjected to unusually severe physical or mental strain of any kind (e.g. infection, surgery, trauma) while you are being treated with prednisolone. The dose may need to be increased.

Increased susceptibility to infections
Prednisolone treatment can reduce your resistance to infections, making it easier for you to contract infections during treatment. Chickenpox and measles can become more serious when taking cortisone preparations. Therefore, if you have not previously had these diseases, you should avoid exposing yourself to chickenpox or measles during treatment and talk to a doctor straight away if this should still happen.
- You are more likely to develop infections whilst taking Prednisolone Tablets, and any existing infections may become worse, especially during periods of stress. Certain infections can be serious if not controlled.
- You can become seriously ill very ill if you get chickenpox while taking Prednisolone. You should avoid contact with people who have chickenpox or shingles whilst taking, and for up to 3 months after you have stopped taking, Prednisolone Tablets. Do not stop taking Prednisolone Tablets.
- You should avoid contact with people who have measles.

If you need to be vaccinated during prednisolone treatment, tell your doctor about your treatment before you receive the vaccination.

Tumour lysis syndrome can occur when corticosteroids are used in cancer treatment. Tell your doctor if you have cancer and have symptoms of tumour lysis syndrome such as muscle cramps, muscle weakness, confusion, irregular heartbeat, vision loss or disturbances, and shortness of breath.

Corticosteroids can cause growth retardation in infants, children and adolescents, and therefore long-term use should be avoided. If long-term use is necessary, the growth of infants and children will be closely monitored by the physician.

Other medicines and Prednisolone
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines bought without a prescription. This is because Prednisolone can affect the way some medicines work. Also some medicines can affect the way Prednisolone works.

In particular, tell your doctor or pharmacist if you are taking any of the following, as your doctor may want to change the dose of Prednisolone, or the other medicine:
- rifampicin, isoniazid (to treat tuberculosis)
- blood thinner
- carbamazepine, phenobarbital, phenytoin (Anti-epilepsy drug)
- anticholinergics (e.g. medicines for Parkinson's disease or asthma)
- cholinesterase inhibitors (for myasthenia gravis or Alzheimer's disease)
- Insulin or diabetes drug in the form of tablets. Cortisone preparations can impair the blood sugar lowering effect of diabetes drugs
- cobicistat (for HIV infection)
- oestrogens (e.g. birth control pills)
- acetylsalicylic acid or non-steroidal anti-inflammatory drugs (NSAIDs) (used to treat pain and inflammation). The risk of peptic ulcer may increase when combined with cortisone preparations
- thiazides, furosemide, ethacrynic acid (potassium lowering diuretics)
- xanthines (e.g. theophylline, for treating asthma)
- beta-2 stimulants (e.g. salbutamol, terbutaline, salmeterol, formoterol, for treating asthma)
- amphotericin B (antibiotic for fungal infection).

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)
If you need to be vaccinated, tell your doctor that you are taking Prednisolone Tablets.

Prednisolone with food and drink
Avoid eating liquorice whilst taking Prednisolone.

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.
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.

Driving and using machines
Dizziness, visual disturbances and fatigue can occur when using prednisolone. If you experience such symptoms, do not drive or use machines. You are responsible for assessing whether you are in a position to drive a motor vehicle or perform work that requires increased attention. One of the factors that may affect your ability in these respects is the use of drugs because of their effects and / or side effects. A description of these effects and side effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are unsure.

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.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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. You should check with your doctor or pharmacist if you are not sure.

Prednisolone tablets should be taken following a meal to reduce the risk of gastric irritation.

Different illnesses require different doses of Prednisolone Tablets. Depending on your illness your daily dose may be between 5 and 60 mg. In some cases you may be instructed to take it every other day. Your doctor will decide when and how to treat you with Prednisolone Tablets.

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. This may depend on your illness, your dosage and how long you have been taking this medicine. In all cases you should be careful to follow any changes your doctor makes.
Whilst you are taking Prednisolone Tablets, if you develop chickenpox, shingles, measles or any infection tell your doctor straight away (refer to section 2 'Increased susceptibility to infections').

Your doctor will give you a Steroid Treatment Card. You must carry it with you at all times. You should show your Steroid Treatment Card to anyone who is giving you treatment such as a doctor, nurse or dentist.

Mental problems while taking Prednisolone Tablets
Mental health problems can happen while taking steroids like Prednisolone Tablets (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 occur, 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 occurred when doses are being lowered or stopped.

Use in 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.

If you take more Prednisolone than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Show any leftover medicines or the empty packet to the doctor.

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

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