Prednisolone 2.5mg tablets
(enteric-coated)

- **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 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 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**.
- The full name of this medicine is Prednisolone 2.5mg Tablets (enteric coated) but within this leaflet it will be referred to as Prednisolone tablets.

**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.

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1. **What Prednisolone tablets are and what they are used for**
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.
2. **Before you take Prednisolone tablets**

**Do not take** Prednisolone tablets if you:
- are **allergic** (hypersensitive) to prednisolone or any of the other ingredients in Prednisolone tablets (see section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- have **cold sores** that affect the eyes
- have an **untreated infection**.

**Check with your doctor or pharmacist** before taking Prednisolone tablets if you:
- have been in contact with anyone who has **chickenpox**, **shingles** or **measles**. Contact your doctor immediately for advice
- have or have a family history of **diabetes** or **glaucoma**
- have **brittle bones**, **high blood pressure**, a recent **heart attack**, a **stomach ulcer**, an **underactive thyroid gland** or **tuberculosis**
- have taken prednisolone tablets (or a similar medicine) before and had muscular problems (**steroid myopathy**)
- have **heart**, **kidney** or **liver** disease
- suffer or have suffered from any **mental illness**
- are being treated with **vaccines**
- have **ever had severe depression** or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Prednisolone tablets or **any of your close family** has had these illnesses

**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 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.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription:
- antacids – do not take at the same time as the Prednisolone tablets
- diuretics (‘water tablets’)
- medicines to treat epilepsy such as carbamazepine, phenobarbital, phenytoin, primidone
- medicines for diabetes including insulin
- medicines to treat infections such as rifabutin, rifampicin, amphotericin, ketoconazole, tetracyclines
- medicines used to treat cancer such as methotrexate, etoposide
- anticoagulant drugs used to thin blood
- oral contraceptives (the ‘pill’)
- other non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin
• mifepristone (used for abortion), ciclosporin, acetazolamide, beta-2-agonists, theophylline, carbenoxolone, aminogluthimide or carbimazole.

**Driving and using machines**
If you do not have enough sleep you may be less alert and patients should make sure they are not affected before driving or operating machinery.

**Pregnancy and breastfeeding**
Ask your doctor or pharmacist for advice before taking this medicine.

**Sugar intolerance**
If you have been told by your doctor that you have an intolerance to some sugars, contact them before taking this medicine, as it contains lactose.

If you see another doctor or go into hospital, let them know what medicines you are taking.

3. **How to take Prednisolone tablets**

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 Prednisolone tablets exactly as your doctor has told you, especially if you are elderly. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets **whole, with a little water as a single dose** in the morning after breakfast unless otherwise directed by the doctor. **Do not chew** or **cut** the tablets.

**The usual doses are:**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>General conditions</td>
<td>5-60mg daily</td>
</tr>
<tr>
<td>Allergic and skin disorders</td>
<td>5-15mg daily</td>
</tr>
<tr>
<td>Blood disorders</td>
<td>15-60mg daily</td>
</tr>
<tr>
<td>Collagenosis</td>
<td>20-30mg daily</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>10-15mg daily</td>
</tr>
</tbody>
</table>

Doses will be decided for children aged 1-17 years and the elderly.

Once a dose is established, it may be changed to use the lowest effective dose depending on your response to the drug.

If you are diabetic, you may find that you need to take more medication to balance the effect of Prednisolone tablets. You should discuss this with your doctor.

Your doctor should check your progress at regular visits. Also, your progress may have to be checked after you have stopped using this medicine, since some of the effects may continue.

**If you forget to take Prednisolone tablets**
If you forget to take a dose, take one as soon as you remember and then your next dose at the usual time. **Never** take two doses at the same time.
If you take more Prednisolone tablets 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.

If you stop taking Prednisolone tablets
If you stop taking the tablets suddenly you may develop muscle or joint pain, conjunctivitis, fever, weight loss, painful itchy skin lumps or runny nose. **Talk to your doctor before** you stop taking the tablets and follow their advice.

4. Possible side effects

Like all medicines, Prednisolone tablets can cause side effects, particularly when you first start taking it although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

**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.

**Tell your doctor straight away** if the following happens:
- inflammation of the pancreas (very severe abdominal pains)
- steroids including Prednisolone 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 tablets:
  - 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 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.

**Tell your doctor** if the following occur:

**Infections** - lowered resistance to infections, such as a cold, existing eye infections may become worse or symptoms of a previous infection such as tuberculosis (TB) may happen more easily. This is especially important regarding chickenpox or measles.

**Stomach and intestines** – increased appetite, indigestion, a feeling of being full or bloated, very sore throat and white areas inside your mouth (oral thrush), feeling sick, weight gain, stomach ulcers.

**Heart** – high blood pressure.

**Nervous system** – unusual tiredness or weakness, nervousness, worsening of schizophrenia, increased pressure in the skull (causing painful eyes, changes in vision or a bad headache, especially behind your eyes).

**Skin** – reddish purple lines, thin skin, unusual bruising, acne, wounds that will not heal.

**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).

**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 infancy, childhood and adolescence may be reduced.

**Kidney** - urinating at night, water and salt retention.

**Blood** - blood clots, changes in the balance of minerals in the blood (detected by a blood test).
Eyes – cataracts, increased pressure in the eye (glaucoma), thinning of the tissues of the eye, pressure on the nerve of the eye.
Withdrawal symptoms – muscle or joint pain, conjunctivitis, fever, weight loss, runny nose and painful, itchy skin lumps.

5. How to store Prednisolone tablets

Keep out of the reach and sight of children.
Store in a cool dry place.
Do not use Prednisolone tablets after the expiry date stated on the label, carton or bottle. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Prednisolone tablets contain
• The active substance (the ingredient that makes the tablets work) is prednisolone.
• The tablet also contains lactose, maize starch, microcrystalline cellulose and magnesium stearate.
• The tablet coating contains colloidal silicon dioxide, hydroxypropylmethylcellulose (E464), iron oxide (E172), macrogol, polyvinyl acetate phthalate, poly (vinyl alcohol), sodium alginate (E401), sodium hydrogen carbonate (E500), stearic acid, talc, titanium dioxide (E171), triethyl citrate (E1505).

What Prednisolone tablets look like and contents of the pack
Prednisolone 2.5mg are circular, dark brown, enteric/film-coated tablets
Pack sizes are 100.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK

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