



PACKAGE LEAFLET:
INFORMATION FOR THE USER
PREDNISOLONE TABLETS BP
1 mg and 5 mg
prednisolone

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.

Important things you need to know about Prednisolone Tablets

- Prednisolone is a steroid medicine, prescribed for many different conditions, including serious illnesses.
- You need to take it regularly to get the maximum benefit.
- Do not 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 (see section 4). Some side effects 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 round face (see section 4).
- If you take this medicine 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.

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 Tablets are and what they are used for
2. What you need to know before you take Prednisolone Tablets
3. How to take Prednisolone Tablets
4. Possible side effects
5. How to store Prednisolone Tablets
6. Contents of the pack and other information

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. What you need to know before you take prednisolone tablets

Do not take Prednisolone Tablets:

- if you are **allergic** to prednisolone or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include:
 - rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have an **infection** that affects your whole body (systemic infection), which is not already being treated (such as measles, chickenpox or shingles)
- if you are suffering from a **herpes** infection of the eye.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Prednisolone Tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Prednisolone Tablets:

- have or 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.
- have or have ever had **mental problems** such as 'depression' or 'psychoses'
- have **epilepsy** (fits)
- or anyone in your family has **diabetes**
- have **high blood** pressure
- have **kidney, liver or heart** problems
- have brittle or weak bones called **osteoporosis**
- are receiving treatment for a condition called myasthenia gravis (**a rare muscular disorder**)
- have ever had **blood clots** (deep vein thrombosis or thromboembolism)
- or anyone in your family has an eye problem called **glaucoma**
- have or have ever had a **stomach ulcer**
- have or have ever had a bad reaction such as muscle weakness to any **steroid**

- have been in contact with anyone who has chickenpox, shingles or measles. **Contact your doctor immediately for advice**
- have or have ever had '**tuberculosis**' (TB)
- have **hypothyroidism**
- are receiving any **vaccines** (please see below, "Vaccinations")
- have 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.

If any of the above applies to you or if you are not sure, talk to your doctor before taking this medicine. Your doctor may want to see you more often during your treatment.

Contact your doctor if you experience blurred vision or other visual disturbances.

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 your 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.

Children and adolescents

Prednisolone Tablets can slow down normal growth during infancy, childhood and adolescence, therefore long-term treatment should be avoided when possible. The growth and development of infants and children should be closely monitored. Talk to your doctor for further information.

Elderly

Close clinical supervision is required to avoid life threatening reactions. Talk to your doctor for further information.

Other medicines and Prednisolone 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. In particular tell your doctor if you are taking any of the following:

- antivirals (e.g. ritonavir or cobicistat)
 - medicines for thinning your blood (e.g. warfarin)
- insulin or oral medicine for diabetes
- carbamazepine, primidone, aminoglutethimide phenobarbital or phenytoin (for epilepsy)
- medicines for high blood pressure (including diuretics, acetazolamide, loop diuretics, thiazide diuretics, carbenoxolone or theophylline)
- cardiac glycosides (for heart problems)
- medicines which contain oestrogens, including oral contraceptives (the 'pill')
- rifamycins, rifabutin, rifampicin, erythromycin, troleandomycin, amphotericin or ketoconazole (for bacterial or fungal infections)
- bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol or terbutaline (to treat asthma)
- non-steroidal anti-inflammatory medicines (NSAIDs) (e.g. indomethacin, aspirin or ibuprofen)
- ciclosporin (used to suppress the immune system)
- methotrexate (used to treat autoimmune conditions)
- mifepristone (used for abortion)
- somatropin (growth hormone).

Vaccinations

If you have just had any injections or vaccinations, tell your doctor before you take Prednisolone Tablets. If you are going to have any injections or vaccinations, tell your doctor or nurse that you are taking Prednisolone Tablets. This includes those needed for a foreign holiday.

Some vaccines should not be given to patients taking Prednisolone Tablets.

This is because Prednisolone Tablets can affect the way some vaccines work. Talk to your doctor if you are not sure.

Pregnancy and breast-feeding

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.

Driving and using machines

There is no evidence to suggest that prednisolone has any affect on the ability to drive or use machines.


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.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. is essentially 'sodium-free'.

ARTWORK DETAIL LABEL

Product	Prednisolone Tablets 1mg & 5mg			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	190 x 310 mm	Pack	----	
New Item Code	1049458	Old Item Code	1047129	
Colour Shades	 Black	No. of Colours	1	
Change Control No.	PC-ODF/2023/515 - Record Number: 394670		Artwork Version	10.0
Design/Style	Front & Back side printing, to be supplied in the Unfolded size.			
Substrate	60 GSM Paper.			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

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 this medicine exactly as your doctor has told you, especially if you are elderly. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole, with a little water as a single dose in the morning after breakfast unless otherwise directed by the doctor.

The recommended dose is:

Adults: 20 to 60 mg daily initially (higher doses may be required for specific conditions), reducing to a maintenance dose of 5 to 20 mg daily.

Children and adolescents: Children do not take as many tablets as adults. Your doctor will suggest the correct number of tablets for them to take.

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 take more Prednisolone Tablets than you should

If you (or someone else) take more tablets than you should, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Prednisolone Tablets

If you forget to take a dose, take one as soon as you remember and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Prednisolone Tablets

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.

If you suddenly stop taking your medicine the following side effects can occur: lack of appetite, feeling sick, being sick, tiredness, skin peeling, inflammation of the inside of the nose, inflammation (swelling and redness) of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids), muscle or joint pain, fever, headache, weight loss, painful itchy skin lumps or low blood pressure. If you notice any of these symptoms please contact your doctor as soon as possible.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

You may experience side effects particularly when you first start taking this medicine. Talk to your doctor or pharmacist if you notice any of the following effects or any effects not listed in this leaflet.

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 you experience any of the following:

- 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. These side effects include:

- 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 (hallucinations). Having strange and frightening thoughts, changing how you act or having feelings of being alone
- feeling dependant or addicted to this product.

Tell your doctor if you experience any of the following side effects which have been reported.

Not known (frequency cannot be estimated from the available data):

- high blood pressure, congestive heart failure in those already at risk, slow heart rate
- increased appetite, weight gain, indigestion, diarrhoea, feeling sick, feeling bloated, stomach pain, ulcer in the gullet (causing a burning pain in the chest, difficulty swallowing), thrush in the gullet, stomach ulcers which may burst and cause bleeding
- brittle bones (osteoporosis) or wasting of bones (avascular osteonecrosis), broken bones, bone pain, muscle weakness and pain, torn tendons
- dizziness, spinning sensation, headache, difficulty in sleeping, worsening of epilepsy, behaviour changes, irritability, nervousness

- difficult healing of wounds, unusual increase in hair growth on body or face, skin rashes, unusual bruising, thinning of the skin, acne, appearance of reddish purple lines, spider veins, increased sweating, urticaria, itchy skin, absence of reaction to skin tests
- filling or rounding of the face (Cushing's syndrome), periods become irregular or stop completely, changes in blood glucose levels,
- water and salt retention, loss of potassium from the body (can cause numbness or tingling, muscle twitching), changes to nitrogen and calcium levels in the body (can cause muscle wasting, tingling sensations, muscle aches or spasms).
- 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
- blood clots, increase in the number of white blood cells
- increased pressure in the eye, glaucoma (can cause pain and changes to vision), cataracts, thinning of the tissue of the eye, bulging of the eye, worsening or viral/fungal eye disease, blurred vision, central serous chorioretinopathy (causing blind spots, distortion of straight lines and objects appearing smaller/further away, blurred vision)
- tiredness, feeling of general discomfort and illness (malaise), increased risk of infections, previous infections such as tuberculosis (TB) may reoccur more easily, withdrawal symptoms (see 'If you stop taking Prednisolone Tablets').

Additional side effects in children and adolescents

Suppression of the hypothalamo-pituitary adrenal axis (may cause tiredness, frequent infections, depression, anxiety), reduced growth in infancy, childhood and adolescence, raised pressure in the skull (causing pain behind the eyes).

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 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 tablets

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 label. The expiry date refers to the last day of that month.

Store below 25°C in a dry place, protect from light.

Do not use this medicine if you notice visible signs of deterioration. 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 is Prednisolone.

The other ingredients are lactose (see section 2), maize starch, sodium starch glycollate, stearic acid, magnesium stearate, colloidal silicon dioxide, starch paste 15%.

What Prednisolone Tablets looks like and contents of the pack Description: *Prednisolone Tablets BP 1 mg:* White, circular normal convex tablets.

Prednisolone Tablets BP 5 mg: White, circular flat beveled edged tablets with breakline on one side and plain on the other side.

Contents of pack: Polypropylene tubes with low density polyethylene caps in pack sizes of 100, 250, 500 and 1000 tablets

Al/PVC blisters strips enclosed in an outer carton, pack sizes 28 or 56 tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre,
Dwight Road, Watford,
WD18 9SS
United Kingdom

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PL 138060036
PL 138060037

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BACK PAGE

190 x 310 mm

ARTWORK DETAIL LABEL

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