

PREDNISOLONE 5mg TABLETS BP

RelonChem

PACKAGE LEAFLET: INFORMATION FOR THE USER

The product name is Prednisolone 5mg Tablets BP which is referred to as Prednisolone Tablets in the leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **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 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 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.

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please 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 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 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. 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. 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 Prednisolone Tablets (listed in section 6).
- (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 from measles, chickenpox or shingles in the last three months.

Warnings and precautions

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

- have or have ever had
 - severe depression or manic-depressive illness (bipolar disorder). This includes having had

depression before or whilst taking steroid medicines like 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)
- 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 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. Contact your doctor if you experience blurred vision or other visual disturbances.

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.

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)
- **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
- medicines used to treat asthma (e.g. theophylline, bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline)
- medicines to treat **fungal infections** such as amphotericin and 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 (e.g. ephedrine (a nasal decongestant))
- 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)
- 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 and cobicistat).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

Driving and using machinery
This medicine should not affect your ability to drive or use machines.

Pharmacode

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 Prednisolone Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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

Use in children and adolescents
Children above 2 years - the doctor decides the most appropriate dose to treat your child. Children under 2 years - may be treated in the hospital Treatment for up to three days is usually enough, but may be longer.

The tablet can be divided into equal doses.

Method of administration
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.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you take more Prednisolone Tablets than you should
If you take more 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 Prednisolone Tablets
If you forget to take 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.

If you stop taking Prednisolone Tablets
Do not stop taking the tablets unless you have been instructed by your doctor, even if you feel better. If you stop taking the medicine unsupervised it can still 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 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. 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 the signs of an allergic reaction.

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

Not known: frequency cannot be estimated from available data

- generally felling 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
- slow heart rate
- 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 (sodium and potassium salts)
- an increase in the number of white blood cells
- formation of blood clots
- blurred vision
- 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.
- long term use of high dose steroids, may lead to the weakening of the immune system, which can increase the risk of malignancy.

Kaposi's sarcoma (a type of cancer consisting of raised, red, purple or brown skin lesion) has also been reported to occur in patients receiving corticosteroids. Stopping treatment may alleviate these symptoms. Prednisolone Tablets can make it easier for you to pick up infections which may very rarely be fatal. Infections such as chickenpox and measles can be made worse or TB (tuberculosis) may recur. If any of the side effects become 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 or pharmacist. 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 package. The expiry date refers to the last day of that month. Do not store above 25°C for tablets stored in polypropylene homopolymer containers with either low density polyethylene caps or LDPE/HDPE mixture caps. Medicinal product stored in blisters do not require any special storage conditions. 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
Each tablet contains the active ingredient prednisolone 5 mg. The other ingredients are Lactose, maize starch and magnesium stearate.

What Prednisolone Tablets look like and the contents of the pack
The tablets are white, round tablets scored on one side. Available in 28's, 30's, 500's and 1000's.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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POM
This leaflet was last revised in April 2021.

Pharmacode

400 mm

400 mm

160 mm

160 mm