

PREDNISON

prednisone

1mg, 2.5mg, 5mg and 20mg Tablets

What is in this leaflet

Please read this leaflet carefully before you start using PREDNISON.

This leaflet answers some common questions about PREDNISON. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using PREDNISON against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PREDNISON is used for

The name of your medicine is PREDNISON tablet. It contains the active ingredient prednisone.

Prednisone belongs to a group of medicines called corticosteroids which are a synthetic version of a naturally occurring body hormone called cortisol.

PREDNISON is used for a wide range of disorders, some of these are:

- severe allergies
- severe or chronic asthma
- skin problems
- arthritis
- inflammatory diseases of the bowel
- cancer
- "auto-immune" diseases

It is also used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body.

These symptoms can occur in response to injury or can be caused by many different conditions.

PREDNISON works by entering inflammatory cells and blocking the inflammatory reaction. It is only able to prevent or reduce symptoms of your condition, it does not cure it.

Your doctor may have prescribed PREDNISON for another reason.

Ask your doctor if you have any questions about why PREDNISON has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

PREDNISON should only be given to children under your doctor's supervision as special care needs to be taken when administered to children.

Before you use PREDNISONONE

When you must not use it

Do not use PREDNISONONE if:

- **You are hypersensitive to, or have had an allergic reaction to prednisone or prednisolone or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **You have the following health/medical conditions:**
 - Current serious or uncontrolled infection unless specific medication is being taken for this.
 - Live virus immunisation
 - Pancreatitis (except pancreatitis caused by sarcoidosis an inflammatory disease)
- **The expiry date (EXP) printed on the pack has passed.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using PREDNISONONE, talk to your doctor.

Before you start to use it

Tell your doctor if:

You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

You have or have had any medical conditions, especially the following:

- a current serious or uncontrolled infection, including fungal infections
- recent surgery or serious injury
- diabetes mellitus (sugar diabetes)
- osteoporosis (softening of the bone)
- a stomach ulcer or other stomach or intestinal problems
- liver, kidney or heart disease
- tuberculosis
- epilepsy
- muscle weakness
- glaucoma (high pressure in the eye), cataracts, blurred vision or other visual disturbances
- thyroid disease
- high blood pressure.

You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

You are currently breastfeeding or you plan to breast-feed.

Prednisone can pass into breast milk and may affect your baby. It is not recommended that you take prednisone whilst you are breast feeding. Your doctor will discuss with you the risks and benefits of taking prednisone when breast-feeding.

You are planning to have surgery or an anaesthetic.

You are currently receiving or are planning to receive dental treatment.

If you have not told your doctor about any of the above, tell them before you start using PREDNISONONE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking PREDNISONONE.

Some medicines may interfere with PREDNISONONE. These include:

- antacids (in large amounts)
- medicines for diabetes
- some medicines for heart disease
- medicines for removal of fluid (diuretics)
- some medicines for epilepsy
- some types of antibiotics
- potassium or salt supplements
- immunisations or vaccines.

These medicines may be affected by PREDNISONONE, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with PREDNISONONE.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking PREDNISONONE.

How to use PREDNISONONE

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

The label should be carefully read.

How to take it

Take with food and swallow the tablet(s) with a full glass of water.

How much to take

The smallest dose which is effective or produces adequate control should be used. It may be necessary to increase dosage temporarily during maintenance therapy or during a steroid withdrawal programme for flare-ups of the underlying disease or for major stress such as infection or trauma.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition, your response to the medicine and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

When the medicine is being reduced or withdrawn the dosage must be tapered gradually. **Suddenly stopping the medicine can be dangerous.**

When to take it

How often this medicine can be taken may vary depending on what condition is being treated. It can be taken once daily, several times a day or on alternate days (every other day).

If you take it once a day or every second day, then it is best taken at breakfast time. If it needs to be taken more than once a day, then space it out during the day.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Abrupt cessation of prednisone therapy should be avoided. When the medicine is being reduced or withdrawn the dosage must be tapered gradually. **Suddenly stopping the medicine can be dangerous.**

Your doctor will advise you when you can stop taking PREDNISONE completely.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

While you are using PREDNISONE

Things you must do

Take your medicine exactly as your doctor has prescribed.

Immediately stop taking PREDNISONE and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking PREDNISONE.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking PREDNISONE.

Always discuss with your doctor any problems or difficulties during or after taking PREDNISONE.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough PREDNISONE to last weekends and holidays.

Things you must not do

Do not give PREDNISONE to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other condition unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor. Do not stop taking PREDNISONE suddenly unless advised by your doctor. If you stop taking it suddenly, the symptoms of your condition may return or you may develop symptoms of cortisol deficiency such as fainting, weakness, restlessness, nausea, vomiting, headache, dizziness, muscle weakness or joint pain.

Do not have any immunisations (particularly with "live" vaccines such as measles, oral polio or yellow fever) without your doctor's approval while you are being treated with PREDNISONE.

Do not take any other medicine while you are taking PREDNISONE without first telling your doctor.

Do not take PREDNISONE for a longer time than your doctor has prescribed.

Things to be careful of

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how PREDNISONONE affects you. PREDNISONONE is likely to produce minor or moderate adverse effects on the ability to drive or use machinery.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much PREDNISONONE.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using PREDNISONONE or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or if you notice any of the following:

This list includes the most common side effects.

Short term use

When prednisone is taken for short periods of time it is unlikely to cause any problems.

Tell your doctor if you notice any of the following side effects and they worry you:

- mood changes
- nausea (feeling sick)
- vomiting
- anorexia (which may result in weight loss)
- increased appetite (which may result in weight gain)
- stomach bloating or irritation
- diarrhoea or constipation.

Long term use

When prednisone is taken for long periods of time and in high doses the risk of side effects is greater.

Tell your doctor if you notice any of the following and they worry you:

- general changes to the body:
 - bloating and rounding of the face (moon face)
 - headache
 - dizziness
 - weight gain
 - redistribution of body fat
 - water retention leading to swollen legs and feet, high blood pressure or an irregular heart beat
 - cramps or weakness in the muscles of the arms and legs
 - slowed growth in children irregular menstrual periods.
- changes to the skin:
 - acne
 - red or flushed face extra hair growth

- red or purple streaks
- easy bruising
- skin thinning increased sweating poor wound healing.
- changes to the immune system:
 - an increased seriousness or frequency of infections.
- changes in behaviour:
 - excessive mood swings (such as changes in personality)
 - anxiety or nervousness restlessness
 - trouble sleeping.
- changes in eyes:
 - decreased or blurred vision
 - eyes sticking out too far
 - cataracts.

Tell your doctor immediately if you notice any of the following.

These may be serious side effects. You may need medical attention.

- severe stomach or intestinal pain
- epileptic fits
- sudden changes in your vision
- symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heart beat
- psychiatric disturbances.

If you or someone you know or care for experience any of the following, stop taking prednisone and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Some side effects can only be detected by your doctor. So it is important to visit your doctor for regular check-ups when PREDNISONE is taken for long periods of time.

Such side effects can include:

- osteoporosis or other changes in bone which can result in an increased chance of fractures due to brittleness or softening of the bone.
- changes in other hormone levels in your body
- changes in the body's ability to handle glucose (steroid diabetes)
- effects on the parathyroid and thyroid glands which control calcium and body metabolism
- increased amounts of cholesterol in the blood
- changes to your white blood cells
- changes to your nervous system which may affect the way your nerves work
- changed sperm count
- increased blood pressure
- increased pressure in the skull
- increased pressure in the eye (glaucoma).

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using PREDNISONE

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

PREDNISONONE 1mg tablets are round, white, biconvex, 5.5mm in diameter and identified P over 1 on one side.

PREDNISONONE 2.5mg tablets are round, white, biconvex, 6.0mm in diameter and identified P over 2.5 on one side.

PREDNISONONE 5mg tablets are round, white, flat-faced with bevelled edges, 6.5mm in diameter and identified P over 5 on one side

PREDNISONONE 20mg tablets are round, pink, biconvex, 6.5mm in diameter and identified P over 20 with a breakline on one side.

PREDNISONONE 1mg, 2.5mg, 5mg and 20mg tablets are available in bottles of 100 or 500 tablets.

* Not all strengths, or pack sizes may be available.

Ingredients

Active ingredient:

Each tablet contains 1mg, 2.5mg, 5mg or 20mg of Prednisone as the active ingredient.

Inactive ingredients:

PREDNISONONE 1mg, 2.5mg, 5mg & 20mg tablets contain the following inactive ingredients:

| | 1mg | 2.5mg | 5mg | 20mg |
|------------------------------|------------|--------------|------------|-------------|
| Lactose monohydrate | ✓ | ✓ | ✓ | ✓ |
| Magnesium stearate | ✓ | ✓ | ✓ | ✓ |
| Maize starch (corn starch) | ✓ | | | |
| Microcrystalline cellulose | ✓ | ✓ | ✓ | ✓ |
| Sodium starch glycolate | ✓ | ✓ | | |
| Colloidal silicon dioxide | | | ✓ | ✓ |
| Croscarmellose sodium | | | ✓ | ✓ |
| Erythrosine (FD&C Red No. 3) | | | | ✓ |

This medicine is gluten free.

This medicine contains lactose.

PREDNISONONE 20mg tablets contain FD&C Red No. 3 as colourant

Sponsor Details

PREDNISONONE is supplied in New Zealand by:

Clinect NZ Pty Limited

C/- Ebos Group Limited

108 Wrights Road

Christchurch 8024

New Zealand

Telephone: 0800 138 803

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This leaflet was prepared on 16 June 2021.