Predsone

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PREDSONE?

PREDSONE contains the active ingredient prednisone. PREDSONE is used to treat many different conditions that involve inflammation, as well as to prevent or reduce symptoms associated with these conditions.
For more information, see Section 1. Why am I using PREDSONE? in the full CMI.

2. What should I know before I use PREDSONE?

Do not use if you have ever had an allergic reaction to prednisone, prednisolone, or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use PREDSONE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PREDSONE and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use PREDSONE?

- The dose of PREDSONE varies from patient to patient.
- Your doctor will tell you how much to take each day, and when to take it.
- PREDSONE is best taken with or immediately after food. Swallow the tablet whole with a glass of water.

More instructions can be found in Section 4. How do I use PREDSONE? in the full CMI.

5. What should I know while using PREDSONE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using PREDSONE. • Tell your doctor if your condition worsens or returns while on PREDSONE after your dose has been reduced or stopped. • If you are diabetic, tell your doctor immediately if you notice a change in results of your blood or urine sugar tests while taking PREDSONE. • Tell your doctor immediately if you become pregnant while taking PREDSONE.
Things you should not do	• Do not stop using this medicine suddenly unless advised by your doctor. • Do not have any immunisations without your doctor's approval while being treated with PREDSONE. • Do not give this medicine to anyone else even if their symptoms seem similar to yours.
Driving or using machines	• Take care of when driving, or operating machinery until you know how PREDSONE affects you.
Drinking alcohol	• Check with your doctor or pharmacist before drinking alcohol while you are taking this medicine.
Looking after your medicine	• Protect from light, and store in a cool, dry place under 30°C

For more information, see Section 5. What should I know while using PREDSONE? in the full CMI.

6. Are there any side effects?

Short term use of PREDSONE is unlikely to cause any problems. But if problems do occur, they may likely involve mood changes and disturbances in your digestive system such as nausea, vomiting, anorexia, increased appetite, stomach bloating/irritation, or diarrhoea or constipation. Long term use and higher doses of PREDSONE may have a greater risk of side effects. Serious side effects include severe stomach/intestinal pain, epileptic fits, psychiatric disturbances, sudden changes in your vision, or severe dizziness, fainting, weakness, chest pain, or irregular heartbeat.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

PREDSONE

Active ingredient(s): *prednisone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PREDSONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PREDSONE.**

Where to find information in this leaflet:

1. Why am I using PREDSONE?
2. What should I know before I use PREDSONE?
3. What if I am taking other medicines?
4. How do I use PREDSONE?
5. What should I know while using PREDSONE?
6. Are there any side effects?
7. Product details

1. Why am I using PREDSONE?

PREDSONE contains the active ingredient prednisone. PREDSONE belongs to a group of medicines called corticosteroids. It is a synthetic version of a naturally occurring body hormone called cortisol.

PREDSONE is used in the treatment of many different conditions. Some of these conditions include: severe allergies, severe or chronic asthma, skin problems, arthritis, inflammatory diseases of the bowel, cancer and "auto-immune" diseases.

PREDSONE 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.

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

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

2. What should I know before I use PREDSONE?

Warnings

Do not use PREDSONE if:

- **You are allergic to prednisolone, prednisone or any of the ingredients listed at the end of this leaflet.** Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.
  Always check the ingredients to make sure you can use this medicine.
- **You have a current serious or uncontrolled infection, including fungal infections.**
- **The expiry date on the pack has passed.**
  It may have no effect at all or an entirely unexpected effect if you take it after the expiry date.
- **The bottle shows signs of having been tampered with.**
- **You are using it to treat any other complaints unless your doctor has instructed you to do so.**

Do not give this medicine to anyone else.

Check with your doctor if you:

Have any other 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) or cataracts
- thyroid disease
- high blood pressure
- an overactive thyroid gland (hyperthyroidism)

It may not be safe for you to take PREDSONE if you have any of these medical conditions.

Take any medicines for any other condition

Have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take PREDSONE if you are pregnant or plan to become pregnant unless you and your doctor have discussed the risks and benefits involved.

Do not take it if you are breastfeeding or intend to breastfeed.
It is not recommended for use while breastfeeding as it is found in breast milk.

Use in children

Take special care when giving PREDSONE to children. It should only be given under your doctor's supervision.

If possible, children should not be exposed to common childhood illnesses such as chickenpox or measles while they are taking this medicine. They may suffer from more serious attacks of these illnesses if such exposure occurs.

Children should not be vaccinated with "live" vaccines against common childhood illnesses while they are taking it, as this may result in severe attacks of these illnesses.

Potentially serious side effects can occur in children and growing teenagers who are taking corticosteroids. Some of these include obesity, slowed growth, osteoporosis (softening of the bone) and changes to the adrenal glands.

Use in the elderly

Elderly patients may be more sensitive to the effects or side effects of this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with PREDSONE and affect how it works. 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.

You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PREDSONE.

4. How do I use ?

How much to take

- Your doctor will tell you how much PREDSONE to take.
- The dose will depend on the condition being treated and your response to the treatment. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

How to take it

- Swallow the tablet whole with a glass of water.

When to take it

- PREDSONE is best taken with or immediately after food.
- How often PREDSONE 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.

How long to take it for

- **Continue taking PREDSONE for as long as your doctor or pharmacist tells you.**
  This will depend on your condition and on your response to treatment. Some people will need this medicine for only short periods of time whilst others may require long term therapy.
- **Do not miss any doses and do not stop taking the medicine even if you feel better.**
  Missing doses may make your symptoms worse.

What to expect

Individuals will vary greatly in their response to PREDSONE. Your doctor will check your progress at regular intervals.

If you forget to take PREDSONE

If you miss a dose of this medicine the decision of whether you should take it or not will depend on how many times a day you take PREDSONE.

If you are taking PREDSONE:

- Once a day -
  If you miss a dose and remember in less than 12 hours, take it straight away, then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.
- Several times a day -
  If you miss a dose and it is more than 2 hours before your next dose is due, take it straight away, then continue as you normally would.
  If it is less than 2 hours to your next dose, skip the dose you have missed but be sure to take the next dose when you are meant to.

- On alternate days -
  If you miss a dose and remember it the same morning, take it straight away then continue as you normally would. If you do not remember the missed dose until later, wait and take it the following morning. Then skip a day before continuing your regular dosage schedule.

Do not try to make up for missed doses by taking more than one dose at a time.
If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much PREDSONE

If you think that you have used too much PREDSONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PREDSONE?

Things you should do

- **Take PREDSONE exactly as your doctor has prescribed.**
  If you do not follow your doctor's instructions, you may not get improvement in the symptoms of your condition. Try not to miss any doses and take the medicine even if you feel well.
- **Tell your doctor if your condition returns or becomes worse after your dose of PREDSONE has been reduced or treatment has been stopped.**
- **Tell any other doctors, dentists and pharmacists who are treating you that you are taking PREDSONE, especially if you are being started on any new medicines.**
- **Tell your doctor, surgeon, or dentist that you are taking PREDSONE if you are about to undergo surgery or an operation.**
  Your dose of this medicine may need to be increased to cover you during the stress of the operation.
- **Ask your doctor when and how you should stop taking PREDSONE.**
  If you have been taking it for a long time your doctor may gradually reduce the amount you are taking over a period of several days, weeks or months before stopping completely. If you have been taking PREDSONE for a short period of time, this may not apply.
- **Tell your doctor straight away if you are a diabetic, and you notice a change in the results of your blood or urine sugar tests.**
  This medicine may affect your blood sugar levels as it can affect the body's ability to handle glucose. For diabetics, this means that your diabetes may become more severe. For others, diabetes may develop for the first time while taking corticosteroids such as PREDSONE.
- **Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using prednisone.** These can be symptoms of a condition called Thyrotoxic Periodic Paralysis, which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with prednisone. You may need additional treatment to alleviate this condition.
- **Tell your doctor immediately if you become pregnant while taking PREDSONE.**

Things you should not do

- **Do not stop taking PREDSONE 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 PREDSONE.**
- **Do not take PREDSONE to treat any other complaints unless your doctor has instructed you to do so.**
- **Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

Things to be careful of

- **Avoid close contact with anyone who has a contagious disease such as measles or chickenpox**.
  Exposure to such diseases while you are taking PREDSONE, particularly if large doses are being taken, can put you at greater risk of developing these diseases if you have not had them before.
- **Tell your doctor straight away if you think you have been exposed to chickenpox or measles.**
  The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of PREDSONE. You should see your doctor for medical advice for any but the most minor infections.

Driving or using machines

As with any new medicine, you should take care when driving or operating machinery until you know how PREDSONE affects you.

Drinking alcohol

Check with your doctor or pharmacist before drinking alcohol while you are taking PREDSONE.
If you drink alcohol while taking PREDSONE you may find that stomach problems occur.

Looking after your medicine

Keep PREDSONE in a cool dry place, protected from light, where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.
A locked cupboard at least one-and-a-half metres above ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PREDSONE.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Short term use When PREDSONE is taken for short periods of time it is unlikely to cause any problems. • 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.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
Long term use When PREDSONE is taken for long periods of time and in high doses the risk of side effects is greater. **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 • painful lumps or swelling under the skin • 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 if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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. These are all serious side effects of PREDSONE. You may need urgent medical attention or hospitalisation.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Some side effects can only be detected by your doctor. So it is important to visit your doctor for regular check-ups when PREDSONE 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
- slow heart rate
- increased pressure in the skull
- increased pressure in the eye (glaucoma).

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.
Other side effects not listed here may occur in some people.

Some people may get other side effects while using PREDSONE.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What PREDSONE contains

Active ingredient (main ingredient)	PREDSONE 1 mg contains 1 mg prednisone per tablet
Other ingredients (inactive ingredients)	• maize starch • lactose monohydrate • povidone • crospovidone • magnesium stearate

Do not take this medicine if you are allergic to any of these ingredients.

PREDSONE tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

What PREDSONE looks like

PREDSONE 1 mg tablets are white, scored, round and biconvex. They are marked with "PN/1" on one side.

Available in bottles of 100.

(AUST R 99792)

Who distributes PREDSONE

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos St
St Leonards NSW 2065
Australia

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