

# Solone<sup>®</sup>

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## 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/pharmacist.

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### 1. Why am I taking Solone?

Solone contains the active ingredient prednisolone. Solone is used to help reduce inflammation in your body or suppress your immune system, when a disease may be due to an auto-immune reaction (where your body fights against itself).

For more information, see Section [1. Why am I using Solone?](#) in the full CMI.

### 2. What should I know before I take Solone?

Do not use if you have ever had an allergic reaction to prednisolone or any of the ingredients listed at the end of the CMI.

There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to

you before taking Solone (see the full CMI for more details).

**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 Solone?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Solone 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 take Solone?**

Follow all directions given to you by your doctor carefully including:

- how many tablets to take each day (the dose needed depends on your medical condition, the treatment you are undergoing and your response to it).
- swallow the tablets with water. More instructions can be found in Section [4. How do I use Solone?](#) in the full CMI.

## 5. What should I know while taking Solone?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Solone.</li><li>• Visit your doctor regularly to check your progress and see whether you need to keep taking Solone.</li><li>• Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not change your dose without first checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Solone affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>

	Drinking alcohol is not recommended whilst you are taking Solone tablets.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store Solone below 30°C in a cool dry place away from moisture, heat or sunlight. Protect from light.</li> </ul>

For more information, see Section [5. What should I know while taking Solone?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include mood changes, nausea, vomiting, increased appetite, stomach issues, diarrhoea or constipation.

Serious side effects include 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 and psychiatric (mental) disturbances.

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.

# Solone<sup>®</sup>

**Active ingredient(s):** *Prednisolone* (Pred-NISS-oh-lone)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Solone. **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 Solone.**

### Where to find information in this leaflet:

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

## 1. Why am I taking Solone?

**Solone contains the active ingredient prednisolone.** Solone belongs to a group of medicines called corticosteroids.

**Solone is used to help reduce inflammation in your body or suppress your immune system, when a disease may be due to an auto-immune reaction (where your body fights against itself).**

**Solone is used to treat a number of medical conditions.**

Your doctor will be able to help decide if Solone is suitable for your condition.

If you have any concerns, you should discuss this with your doctor.

## **2. What should I know before I take Solone?**

### **Warnings**

#### **Do not take Solone if:**

- you are allergic to prednisolone or other cortisone type medications, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
  - urticaria and other skin rashes
  - difficulty breathing
  - swelling of the face or throat
  - faintness.
- you have a peptic ulcer
- you suffer from osteoporosis (brittle bones)

- you have severe disturbances in thoughts, feelings and behaviours (psychoneuroses)
- you have, have had or suspect you have tuberculosis, unless your doctor has prescribed Solone to help treat your tuberculosis
- you have a severe fungal infection in your body
- it is past the expiry date printed on the pack
- if the packaging is torn or shows any signs of tampering.

### **Check with your doctor if you:**

- have or have had any other medical conditions including:
  - congestive heart failure or have any other heart disease
  - myasthenia gravis
  - diabetes
  - kidney failure or high levels of urea in the blood
  - an underactive thyroid gland (hypothyroidism)
  - a stomach ulcer
  - osteoporosis (brittle bone disease)
  - any infection (bacterial or fungal) including viral infections such as chicken pox or measles. Solone may mask some signs of infection, and new infections may appear during their use.
  - scleroderma (also known as systemic sclerosis, an autoimmune disorder). 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.

- take any vaccines. Talk to your doctor before you take live or attenuated vaccines.

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**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Solone is not recommended when breastfeeding as it can be present in breast milk.

## **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 Solone and affect how it works.**

**These include:**

- medicines used to treat upset stomachs such as antacids
- medicines used for diabetes including insulin and oral antidiabetic medicines
- medicines used to treat tuberculosis such as rifampicin
- medicines used to treat fungal infections such as ketoconazole
- some medicines which have a high sodium content and foods with a high sodium content - check with your pharmacist
- some fluid reducing tablets, also called diuretics
- barbiturates, medicine used to treat epilepsy
- high doses of aspirin
- potassium supplements
- growth hormones
- digoxin or digitalis glycosides
- vaccines, live viruses or other immunisations.

The above medicines may either reduce the effectiveness of Solone and/or react with Solone resulting in untoward or sometimes dangerous side effects.

Solone may interfere with laboratory tests that check your thyroid.

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

## 4. How do I take Solone?

### How much to take / use

- The dose needed depends on your medical condition, the treatment you are undergoing and your response to it. The recommended doses are:
  - Adults: 10 mg to 100 mg daily in divided doses.
  - Children: 1 to 5 years: 2.5 mg to 10 mg twice daily.
  - Children: 6 to 12 years: 5 mg to 20 mg twice daily.
- Swallow the tablets with water. If the dose is one-half tablet, there is a break-line on the tablet to help you divide it.
- Follow the instructions provided and use Solone until your doctor tells you to stop. High doses of Solone should be reduced gradually.

### When to take Solone

- Solone should be taken after meals at the time directed by your doctor.

### If you forget to take Solone

Solone should be taken regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as possible, but not later than 4 hours before your next dose.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you take too much Solone**

If you think that you have taken too much Solone, 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.**

If you take too much Solone you may have the following symptoms: weakness, convulsions, dizziness, headache, nausea, vomiting, blurred vision, menstrual irregularities, and symptoms associated with electrolyte and fluid depletion and high blood pressure (hypertension).

## **5. What should I know while taking Solone?**

### **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are using Solone
- Take Solone exactly as your doctor has prescribed.
- Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Solone.
- Tell your doctor if you notice any changes to your eyesight. Prolonged use of Solone may cause eye issues, including cataracts, glaucoma with possible damage to the optic nerves.
- 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 or dose unnecessarily.
- Keep enough Solone to last weekends and holidays.

### **Call your doctor straight away if you:**

- become pregnant while you are taking Solone.

### **Things you should not do**

- Do not stop using this medicine suddenly. Stopping this medicine suddenly on your own accord may cause some unwanted and dangerous effects, or your

condition may reappear. Your doctor will advise you when you can stop taking Solone completely.

- Do not change your dose without first checking with your doctor.
- Do not use this medicine to treat any other complaints unless your doctor says to.
- Do not take any other medicines while you are taking Solone without first telling your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Solone affects you.**

Solone may cause dizziness in some people.

Make sure you know how you react to Solone before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Drinking alcohol is not recommended whilst you are taking Solone tablets.

## **Looking after your medicine**

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

Store Solone below 30°C 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.

Protect from light.

**Keep it where young children cannot reach it.**

## **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?**

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**

<b>Less serious side effects</b>	<b>What to do</b>
These side effects may generally be experienced when Solone is taken for short periods of time:	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● mood changes</li> <li>● nausea (feeling sick)</li> <li>● vomiting</li> <li>● increased appetite (which may result in weight gain)</li> <li>● stomach bloating or irritation</li> <li>● diarrhoea or constipation.</li> </ul> <p>When Solone is taken for long periods of time and in high doses the risk of side effects is greater.</p> <p><b><u>General changes to the body:</u></b></p> <ul style="list-style-type: none"> <li>● bloating and rounding of the face (moon face)</li> <li>● headache</li> <li>● dizziness</li> <li>● high blood pressure</li> <li>● weight gain</li> <li>● redistribution of body fat</li> <li>● water retention leading to swollen legs and feet,</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p>high blood pressure or an irregular heart-beat</p> <ul style="list-style-type: none"> <li>● cramps or weakness in the muscles of the arms and legs</li> <li>● slowed growth in children</li> <li>● irregular menstrual periods.</li> </ul> <p><b><u>Changes to the skin:</u></b></p> <ul style="list-style-type: none"> <li>● acne</li> <li>● red or flushed face</li> <li>● red or purple streaks</li> <li>● easy bruising</li> <li>● skin thinning</li> <li>● increased sweating</li> <li>● poor wound healing</li> <li>● skin rashes.</li> </ul> <p><b><u>Changes to the immune system:</u></b></p> <ul style="list-style-type: none"> <li>● an increased seriousness or frequency of infections.</li> </ul> <p><b><u>Changes in behaviour:</u></b></p> <ul style="list-style-type: none"> <li>● excessive mood swings (such as changes in</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p>personality and loss of contact with reality)</p> <ul style="list-style-type: none"> <li>● anxiety or nervousness</li> <li>● depression</li> <li>● euphoria</li> <li>● restlessness</li> <li>● trouble sleeping.</li> </ul> <p><b><u>Changes in eyes:</u></b></p> <ul style="list-style-type: none"> <li>● decreased or blurred vision</li> <li>● eyes sticking out too far cataracts.</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Severe stomach or intestinal pain</li> <li>● epileptic fits</li> <li>● sudden changes in your vision</li> <li>● symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heart-beat</li> </ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● psychiatric (mental) disturbances.</li> </ul>	

### **Side effects where the frequency is not known:**

- 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.
- Slow heart rate (bradycardia).

### **Side effects detected by your doctor:**

Some side effects can only be detected by your doctor. So it is important to visit your doctor for regular check-ups when Solone 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
- increased blood pressure

- increased pressure in the skull
- increased pressure in the eye (glaucoma).
- rare eye diseases such as central serous chorioretinopathy (CSCR).

**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.

## **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](http://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 Solone contains**

<b>Active ingredient (main ingredient)</b>	Prednisolone
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<p><b>Other ingredients (inactive ingredients)</b></p>	<p>Lactose monohydrate Propyl hydroxybenzoate Maize starch Wheat starch Gelatin Magnesium stearate</p>
<p><b>Potential allergens</b></p>	<p>Contains: Sugars as lactose monohydrate Gluten Hydroxybenzoates Sulfites</p>

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

### **What Solone looks like**

Solone is available in two strengths as follows:

#### **5 mg tablet - AUST R 13469**

White, round, biconvex tablet with a breakline on one side and marking 'L' on other side. It comes in a bottle of 60 tablets.

#### **25 mg tablet - AUST R 13468**

White, round, biconvex tablet with a breakline on one side and plain on other side. It comes in a bottle of 30 tablets.

## **Who distributes Solone**

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

Level 10, 12 Help Street

Chatswood NSW 2067

Telephone: 1800 630 056

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