

# Predsol suppository and retention enema

## 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 PRED SOL?

PRED SOL contains the active ingredient prednisolone (as prednisolone sodium phosphate). PRED SOL is used to treat many types of inflammation in the rectum and large intestine.

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

### 2. What should I know before I use PRED SOL?

Do not use if you have ever had an allergic reaction to PRED SOL 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 PRED SOL?](#) in the full CMI.

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

Some medicines may interfere with PRED SOL 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 PRED SOL?

- Suppository: Insert into the rectum as directed by your doctor at bedtime and/or after morning defecation
- Retention enema: empty into rectum as instructed in Section [4. How do I use PRED SOL](#) at bedtime

More instructions can be found in Section [4. How do I use PRED SOL?](#) in the full CMI.

### 5. What should I know while using PRED SOL?

<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 PRED SOL.</li><li>• Tell your doctor if you feel PRED SOL is not helping your condition or if you have any problems or difficulties during or after using PRED SOL.</li><li>• Tell your doctor if, for any reason, you have not used your PRED SOL as prescribed.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give PRED SOL to anyone else even though their symptoms seem similar to yours.</li><li>• Do not use PRED SOL for other conditions unless your doctor tells you.</li><li>• Do not use PRED SOL for a longer time than your doctor recommends.</li><li>• Do not swallow PRED SOL.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep PRED SOL in a cool dry place, protected from light, where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

Common side effects of PRED SOL include itching and burning. In patients receiving immunosuppressive therapy, use of PRED SOL may worsen pre-existing infection. Serious side effects are rare and may occur if PRED SOL is used for a long time. This includes hypothalamic-pituitary-adrenal (HPA) axis suppression, which your doctor may decide to monitor for. Other serious side effects include sudden changes of vision; convulsions; and signs of allergic reaction - such as 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.

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.

# Predsol suppository and retention enema

Active ingredient(s): *prednisolone sodium phosphate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PRED SOL suppositories and PRED SOL retention enemas.

**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 PRED SOL.**

Where to find information in this leaflet:

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

## 1. Why am I using PRED SOL?

PRED SOL contains the active ingredient prednisolone (as prednisolone sodium phosphate), which is a type of glucocorticoid belonging to a group of medicines called corticosteroids.

PRED SOL suppositories are used in the treatment of many different conditions such as:

- haemorrhagic and granular proctitis (a type of inflammation in the rectum)
- post radiation proctitis (inflammation in the rectum following radiation therapy)
- rectal complications of Crohn's disease (inflammation of the intestine).

PRED SOL retention enemas are used in the treatment of ulcerative colitis and Crohn's disease.

PRED SOL suppositories and PRED SOL retention enemas are for use in the rectum only. They should not be taken by mouth.

**Ask your doctor if you have any questions about why PRED SOL has been prescribed for you.**

Your doctor may have prescribed it for another reason, for example, haemorrhoids.

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

## 2. What should I know before I use PRED SOL?

### Warnings

**Do not use PRED SOL if:**

- **You are allergic to prednisolone 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 any of the following health conditions:**
  - tuberculous and fungal infections (such as tinea, thrush or ringworm) of the skin.
  - acute herpes simplex (such as cold sores, shingles or chicken pox), vaccinia (cow pox), varicella (a rare form of chicken pox).
  - any viral infection.
- **You are currently on oral or intravenous corticosteroid therapy or have markedly impaired circulation (check with your doctor).**
- **The area around the rectum is traumatised or showing signs of inflammation.**
- **The expiry date on the pack has passed.**  
It may have no effect at all or an entirely unexpected effect if you use it after the expiry date.
- **The bottle shows signs of having been tampered with.**

**Check with your doctor if you:**

**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

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

PRED SOL should not be used during pregnancy unless your doctor specifically tells you to.

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

## Use in children

Do not use in children unless specifically directed by your doctor.

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

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

**Some medicines may interfere with PREDsOL and affect how it works. These include:**

- antacids, antidiabetic agents (oral or insulin), digitalis glycosides, diuretics, barbiturates, phenytoin, rifampicin, potassium supplements, ritrodine, foods or medications containing sodium, somatren, somatropin, vaccines, live viruses.
- troleandomycin, ketoconazole may require the dose of PREDsOL to be reduced.
- chronic, high dose aspirin may have its effects reduced so it should be closely monitored.
- The effects of anticoagulants may be variable, so close monitoring is required.

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

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

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

## 4. How do I use PREDsOL?

### How to use it

#### Suppository:

Insert into the rectum gently as directed.

#### Retention enema:

1. The enema may be warmed before use, by placing the bag in a vessel of hot water for a few minutes.
2. Lie down on the left side with the knees drawn up.
3. Remove the stopper from the bag, lubricate the nozzle with petroleum jelly and gently insert about half the length of the nozzle into the rectum.
4. The bag should then be slowly rolled up like a tube of toothpaste until it is emptied, taking a minute or two to do so.
5. The nozzle should then be removed, with the bag still rolled up, and the whole unit discarded.
6. Roll over to lie face down for three to five minutes but you may sleep in any comfortable position.

## When to use it

### Suppository:

Use as directed by your doctor.

The usual dose is one at bedtime and the other after morning defecation.

When response is good, treatment may continue for some months or until investigation shows improvement.

### Retention enema:

Use as directed by your doctor.

The usual dose is one enema at night, on retiring to bed, for two to four weeks.

Treatment may be continued if the response is good but should not be persisted with if response is inadequate.

### How long to use it for

**Continue to use PREDsOL for as long and exactly as your doctor tells you.**

If you use less than you should, it may not work as well and your medical condition may not improve. Using it more frequently may not improve your condition any faster and may cause or increase side effects.

### If you forget to use it

Use it as soon as you remember and then return to your normal dosing time.

If your next dose is almost due, leave using PREDsOL until that time.

**Do not try to make up for missed doses by using more than one dose at a time.**

This may increase the chance of getting an unwanted side effect.

### If it is accidentally swallowed

If you or someone else accidentally swallows PREDsOL, you or they 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 PRED SOL?

### Things you should do

- Tell your doctor if you feel PRED SOL is not helping your condition or if you have any problems or difficulties during or after using PRED SOL.
- Tell all doctors, pharmacists and dentists who treat you that you use PRED SOL.
- Tell your doctor if, you become pregnant while using PRED SOL.
- **Tell your doctor if, for any reason, you have not used your PRED SOL as prescribed.** Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

### Things you should not do

- Do not give PRED SOL to anyone else even though their symptoms seem similar to yours.
- **Do not use PRED SOL for other conditions unless your doctor tells you.** This medicine has been prescribed for you for a specific condition. If you use it for another condition it may not work or may make the condition worse.
- Do not give it to small children.

### Things to be careful of

- **Do not use PRED SOL for a longer time than your doctor recommends.** If you use it for longer than recommended or use more than the prescribed dose, the chances of systemic absorption of the drug through the rectum and the chance of side effects increases.
- Ask your doctor or pharmacist if you are concerned about the length of time you have used this medicine.
- **Do not swallow PRED SOL.** This medicine is only to be used in the rectum.

### Driving or using machines

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

### Looking after your medicine

**Keep PRED SOL in a cool dry place, protected from light, where the temperature stays below 25°C.**

This is especially important for PRED SOL suppository, as it will help to prevent it from melting.

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.

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

**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.

### When to discard your medicine

Discard any unused enema bags three months after first opening the outer plastic bag.

### 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 using PRED SOL.**

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
<p><b>general changes to the body:</b></p> <ul style="list-style-type: none"> <li>• bloating and rounding of the face (moon face)</li> <li>• headache or dizziness</li> <li>• weight gain</li> <li>• redistribution of body fat</li> <li>• water retention leading to swollen legs and feet, high blood pressure</li> <li>• cramps or weakness in the arm or leg</li> <li>• slowed growth in children</li> <li>• irregular menstrual periods.</li> </ul> <p><b>changes to the skin:</b></p> <ul style="list-style-type: none"> <li>• itching and burning</li> <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>• may affect skin test results.</li> </ul> <p><b>changes to the immune system:</b></p> <ul style="list-style-type: none"> <li>• an increased seriousness or frequency of infections.</li> <li>• worsening of pre-existing infection if you are taking other immunosuppressants</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>blurred vision or other eye problems</li><li>symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heart beat</li><li>epileptic fits</li><li>Hypothalamic-pituitary-adrenal (HPA) axis suppression.</li></ul>	<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>

The risk of undesirable effects increases with prolonged use.

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

### Hypothalamic-pituitary-adrenal (HPA) axis suppression

There is a possibility of systemic absorption of prednisolone, especially if PRED SOL is used for a long time. This may result in hypothalamic-pituitary-adrenal (HPA) axis suppression, especially in children.

HPA involve three organs that regulate and maintain hormone levels in the body. Your doctor will decide if there is a need for a test to monitor the hormone levels in the blood.

**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.

**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](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 PRED SOL suppository contains

<b>Active ingredient (main ingredient)</b>	prednisolone 5 mg (as prednisolone sodium phosphate)
<b>Other ingredients (inactive ingredients)</b>	hard fat

There are no preservatives or colouring agents in PRED SOL suppositories.

### What PRED SOL retention enema contains

<b>Active ingredient (main ingredient)</b>	prednisolone 20 mg/100 mL (as prednisolone sodium phosphate)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>sodium hydroxide</li><li>dibasic sodium</li><li>phosphate heptahydrate monobasic sodium phosphate</li><li>disodium edetate</li><li>Nipastat GL75</li><li>purified water</li></ul>

Nipastat GL75 is a preservative which contains methyl hydroxybenzoate, ethyl hydroxybenzoate, propyl hydroxybenzoate, butyl hydroxybenzoate and isobutyl hydroxybenzoate.

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

### What PRED SOL looks like

#### Suppository:

White to off-white bullet shape with no defects.

Available in PVC/PVdC/PE blister packs of 10 suppositories. (AUST R 56510)

#### Retention enema:

A clear, colourless liquid free from haze and substantially free from particulate matter. The solution is sealed in a disposable PVC bag fitted with an individual nozzle.

Each carton contains seven (7) 100 mL bags. (AUST R 12518)

### Who distributes PRED SOL

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos St  
St Leonards NSW 2065  
Australia

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