What is this leaflet

This leaflet answers some common questions about PRED-SOL suppositories and PRED-SOL retention enemas. It does not contain all of 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 PRED-SOL 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 PRED-SOL is used for

The active ingredient in PRED-SOL is prednisolone (as 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.

Do not use PRED-SOL if you are allergic to prednisolone or any of the ingredients listed at the end of this leaflet.
Do not use PRED-SOL if you have:
- 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.

Before you use it

When you must not use it

Tell your doctor if you are:
- allergic to any other medicines or any foods, dyes or preservatives
- you are pregnant or plan to become pregnant
- you are breast feeding or plan to breast feed.

If you have not told your doctor about any of the above, tell them before you use PRED-SOL.
Using other medicines

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

Some medicines may interfere with PRED SOL. These include:

- antacids, antidiabetic agents (oral or insulin), digitalis glycosides, diuretics, barbiturates, phenytoin, rifampicin, potassium supplements, ritodrine, foods or medications containing sodium, somatropin, vaccines, live viruses.
- Troleandomycin, ketoconazole may require the dose of PRED SOL 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 PRED SOL, reduce its own effectiveness and/or react with PRED SOL 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 PRED SOL.

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

How to use it

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.

Things you must 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 immediately if you become pregnant while using PRED SOL.

Things you must not do

Do not give PRED SOL to anyone else even though their symptoms seem similar to yours.

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 PRED SOL 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

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital if you think you or anyone else may have swallowed PRED SOL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must 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, 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.

Tell your doctor immediately if you become pregnant while using PRED SOL.

Things you must not do

Do not give PRED SOL to anyone else even though their symptoms seem similar to yours.
Do not use PREDSOL 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 PREDSOL 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 PREDSOL.
This medicine is only to be used in the rectum.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using PREDSOL.
PREDsOL helps most people with medical conditions listed in the beginning of this leaflet, but it may have unwanted side effects in some people.

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 side effects.

Ask your doctor or pharmacist to answer any questions you may have.
The most common side effects of PREDSOL are itching and burning.

In patients who are receiving immunosuppressive therapy, use of PREDSOL may worsen a pre-existing infection.
The risk of undesirable effects increases with prolonged use.
There is a possibility of systemic absorption of prednisolone, especially if PREDSOL 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 if you notice anything else that is making you feel unwell.
Some people may get other side effects while using PREDSOL.
Do not be alarmed by this list of possible side effects.
You may not experience any of them.

Disposal

If your doctor tells you to stop using PREDSOL, or they pass their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

Suppositories:
White to off-white bullet shape with no defects. Available in blister packs of 10 suppositories.

Retention enemas:
A clear, colourless solution free from haze and substantially free from particulate matter. The solution is sealed in a plastic, disposable bag fitted with an individual nozzle. Each carton contains seven (7) 100 mL bags.

Ingredients

Suppositories:
Active ingredient:
Each suppository contains prednisolone 5 mg (as prednisolone sodium phosphate).
Inactive ingredient:
• hard fat.
There are no preservatives or colouring agents in PREDSOL suppositories.

Retention enemas:
Active ingredient:
Each retention enema contains 20 mg/100 mL of prednisolone (as prednisolone sodium phosphate).
Inactive ingredients:
• sodium hydroxide
• sodium phosphate-dibasic
• sodium phosphate-monobasic
• disodium edetate
• Nipastat GL75
• water-purified.

After using it

Storage

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

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

Do not store PREDSOL or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills.
Heat and dampness can destroy some medicines.

Discard any unused enema bags three months after first opening the outer plastic bag.
Nipastat GL75 is a preservative which contains methyl hydroxybenzoate, ethyl hydroxybenzoate, propyl hydroxybenzoate, butyl hydroxybenzoate and isobutyl hydroxybenzoate.

**Sponsor**

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

**Australian Registration Numbers are:**
- PRED SOL suppositories: AUST R 56510
- PRED SOL retention enema: AUST R 12518.

This leaflet was prepared in October 2011.