

PREDSOL® suppository and enema

prednisolone (as sodium phosphate)

Consumer Medicine Information

What is this leaflet

This leaflet answers some common questions about PREDSOL Suppositories and PREDSOL 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 PREDSOL 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 PREDSOL is used for

The active ingredient in PREDSOL is prednisolone (as sodium phosphate), which is a type of glucocorticoid belonging to a group of medicines called corticosteroids.

PREDSOL 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).

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

PREDSOL suppositories and PREDSOL 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 PREDSOL 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.

Before you use it

When you must not use it

Do not use PREDSOL if you are allergic to prednisolone or any of the ingredients listed at the end of this leaflet.

Do not use PREDSOL 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.

Do not use PREDSOL if the area around the rectum is traumatised or showing signs of inflammation.

Do not use PREDSOL if you are currently on oral or intravenous corticosteroid therapy or have markedly impaired circulation (check with your doctor).

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

Do not use PREDSOL after the expiry date printed on the pack. If you use it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

Do not use PREDSOL if the packaging is torn or shows signs of tampering.

Before you start to 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 PREDSOL.

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 PREDSOL. 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.

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

How to use it

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

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

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 PREDsOL. 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 PREDsOL is not helping your condition or if you have any problems or difficulties during or after using PREDsOL.

Tell all doctors, pharmacists and dentists who treat you that you use PREDsOL.

Tell your doctor if, for any reason, you have not used your PREDsOL 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 PREDsOL.

Things you must not do

Do not give PREDsOL 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 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using PRED SOL.

PRED SOL 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 PRED SOL are itching and burning.

In patients who are receiving immunosuppressive therapy, use of PRED SOL 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 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 if you notice anything else that is making you feel unwell.

Some people may get other side effects while using PRED SOL.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep PRED SOL 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 PRED SOL 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.

Disposal

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

Product description

What it looks like

Suppository:

White to off-white bullet shape with no defects. Available in

PVC/PVdC/PE blister packs of 10 suppositories.

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.

Ingredients

Suppository:

Active ingredient:

Each suppository contains prednisolone 5 mg (as prednisolone sodium phosphate).

Inactive ingredient:

- hard fat.

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

Retention enema:

Active ingredient:

Each retention enema contains 20 mg/100 mL of prednisolone (as prednisolone sodium phosphate).

Inactive ingredients:

- sodium hydroxide
- dibasic sodium phosphate heptahydrate
- monobasic sodium phosphate
- disodium edetate
- Nipastat GL75
- purified water.

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
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Australia

**Australian Registration Numbers
are:**

- PRED SOL suppository: AUST
R 56510
- PRED SOL retention enema:
AUST R 12518.

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