

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rPEDIAPRED®

Prednisolone Solution

Read this carefully before you start taking **PEDIAPRED** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PEDIAPRED**.

What is PEDIAPRED used for?

PEDIAPRED is used to:

- help replace the corticosteroids normally produced by your body, or
- provide relief from inflammation or allergies from many diseases.

It may be given to you as part of a treatment for a problem you may have.

How does PEDIAPRED work?

PEDIAPRED works by lowering the activity of your immune system. PEDIAPRED will slow your body's response to a disease or injury.

What are the ingredients in PEDIAPRED?

Medicinal ingredients: Prednisolone (as Prednisolone Sodium Phosphate)

Non-medicinal ingredients: Artificial raspberry flavor, dibasic sodium phosphate, edetate disodium, methylparaben, purified water, sodium phosphate monobasic, sorbitol.

PEDIAPRED comes in the following dosage forms:

Oral Solution, 5 mg / 5 mL

Do not use PEDIAPRED if:

- you have an untreated systemic fungal infection.
- you are allergic to any ingredients in this drug or the container.
- you have an infection or herpes virus such as chicken pox, measles, hepatitis, herpes, or shingles.
- you experience psychotic episodes that are not controlled by a treatment.
- you have recently received a live vaccine, such as a vaccine for measles, mumps, rubella, or chicken pox.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PEDIAPRED. Talk about any health conditions or problems you may have, including if you:

- AIDS or other infections.
- stomach or intestine problems.
- bone disease.
- high blood sugar (diabetes).

- heart disease or had a heart attack.
- high or low blood pressure.
- kidney disease or stones.
- liver problems like cirrhosis.
- parasites called threadworms.
- lung disease.
- muscle pain or weakness.
- tendon problems.
- skin problems.
- above normal hair growth.
- eye problems such as glaucoma, cataracts, herpes infection, or any problems with the retina.
- have disorders that affect glands and hormones (endocrine system) like:
 - low potassium or calcium.
 - thyroid problems (hypothyroidism).
 - high levels of stress that are not normal.
 - tumors in your adrenal glands.
- certain mental or mood conditions (such as depression, trouble sleeping, mood swings).

Other warnings you should know about:

- If you have scleroderma (systemic sclerosis), a disease that hardens and tightens skin, daily doses of 15 mg or more of PEDIAPRED may increase the risk of scleroderma renal crisis. This can cause blood pressure to rise and less urine to be made.
- If you have never had chicken pox or measles, you should avoid contact with people with chicken pox, shingles and measles.
 - If you were in contact with these infections, tell your healthcare professional right away, even if there are no symptoms.
- Do not get any vaccines while taking PEDIAPRED.
- Other people living in your home should not get the oral polio vaccine. There is a chance they could pass the polio virus on to you.
- PEDIAPRED might affect skin test results.

Steroid Withdrawal Syndrome:

- Stopping the treatment suddenly may cause:
 - **Steroid withdrawal syndrome**
 - **Decreased Adrenal Function** (your adrenal glands do not make enough adrenal hormones),
 - your condition that is being treated to get worse or to come back.

Tumor Lysis Syndrome:

- PEDIAPRED may cause Tumor Lysis Syndrome. This is a problem where large amounts of cancer cells are killed quickly by the cancer treatment. The contents of the dead cancer cells are then released into your blood. Speak to your healthcare professional if you have a cancer that affects your blood. Your healthcare professional should monitor you closely if you have high levels of uric acid in your blood.

See the “Serious side effects and what to do about them” table, below, for more information on these and other serious side effects.

Fertility, pregnancy and breastfeeding:**Male Patients:**

- PEDIAPRED may affect sperm count and how they work in some men. It is not known if this will affect your ability to father a child.

Female Patients:

- Talk to your healthcare professional if you are pregnant, or trying to become pregnant, or are breastfeeding or intend to breastfeed.
- Your healthcare professional will talk to you about the possible serious risks of PEDIAPRED to your unborn baby if you become pregnant.
- If you are pregnant and in your first trimester of pregnancy: Only take PEDIAPRED if you are told to do so by your healthcare professional. They will decide if the benefits outweigh the risks. PEDIAPRED may increase the risk of a baby being born with lip and mouth problems.

Pediatric Patients:

- A child's heart might get thicker than normal while taking PEDIAPRED.
- Children are at higher risk to get disorders that affect glands and hormones, like Cushing's Syndrome, while taking PEDIAPRED.
- PEDIAPRED can affect growth in children.

Geriatric Patients:

- Problems of removing PEDIAPRED from the body can happen in geriatrics.

Driving and Using Machines: PEDIAPRED can cause blurred vision. Before you do tasks which may require attention, wait until you know how you respond to PEDIAPRED.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PEDIAPRED:

- Anticholinesterases, drugs that treat skeletal muscle weakness.
- Coumarin, used to thin the blood.
- Ephedrine, used to prevent low blood pressure.
- Cyclosporin, used to prevent organ transplant rejection.
- CYP3A inhibitors (cobicistat-containing products).
- Digitalis glycosides like digoxin, used to treat heart problems or high blood pressure.
- Anticonvulsants like phenobarbital, phenytoin and carbamazepine, used to treat epilepsy and seizures.
- Rifampin, erythromycin, and fluoroquinolones, antibiotics used to treat infections.
- Diuretics, laxatives, amphotericin B, and tetracosactide, drugs that cause low potassium levels.
- Isoniazid, an antibiotic used to treat tuberculosis.
- Ibuprofen and acetylsalicylic acid, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

- Potassium-depleting agents (e.g. thiazide diuretics).
- Vaccines.
- Salicylates, such as aspirin, used to treat fever, pain, and swelling.
- Antacids, such as calcium carbonate, magnesium hydroxide, or aluminum hydroxide, used to treat stomach upset and heart burn.
- Medicines used to treat diabetes.
- Drugs containing potassium or sodium.
- Alcohol. Stomach problems may happen if you drink alcoholic drinks while being treated with PEDIAPRED.

How to take PEDIAPRED:

- Take exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take PEDIAPRED, by mouth, with food to help prevent an upset stomach.
- Do not give PEDIAPRED to other people.
- Your healthcare professional will monitor your health. They may interrupt, reduce, or stop your dose. This may occur based on your current health, if you take certain other medications or if you have certain side effects.
- Follow your healthcare professional’s instructions if you need to stop taking PEDIAPRED after using it for a long time. You may need to slowly lower the amount of PEDIAPRED you are taking. This is because of the risk for **steroid withdrawal syndrome** if you stop your treatment suddenly.
- Do not stop taking your PEDIAPRED without first talking to your healthcare professional.

Usual dose:

- Take PEDIAPRED as directed by your healthcare professional.
- Do not take more or less than the recommended dose prescribed by your healthcare professional.
- Do not change the dose or schedule unless your healthcare professional tells you to.
- Do not stop taking PEDIAPRED unless your healthcare professional tells you to.

Overdose:

If you think you, or a person you are caring for, have taken too much PEDIAPRED, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of PEDIAPRED is missed and your dosing schedule is:

One dose every other day:

- Take the missed dose as soon as possible if you remember it the same morning. Take the next dose at your regular time.
- If you do not remember the missed dose until later in the day, wait and take it the next morning. Then skip a day and take your next dose at your regular time.

One dose a day:

- Take the missed dose as soon as possible, then take your next dose at your regular time.
- If you do not remember until the next day, skip the missed dose and take your next dose at your regular time. Do not double the dose to make up for a missed dose.

Several doses a day:

- Take the missed dose as soon as possible, then take your next dose at your regular time.
- If you do not remember until your next dose is due, double that dose, then take your next dose at your regular time.

What are possible side effects from using PEDIAPRED?

These are not all the possible side effects you may have when taking PEDIAPRED. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- indigestion
- increased appetite
- nervousness or restlessness
- trouble sleeping
- weight gain
- loss of muscles
- red face
- heavy sweating
- sore throat
- black or tarry stools
- headache

PEDIAPRED can cause abnormal exam, x-ray, urine, blood pressure and blood test results. Your healthcare professional will do some tests before and during your treatment. The healthcare professional will interpret the results. They will tell you if there are any abnormalities in your tests that might need treatment.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Acute kidney failure (severe kidney problems): urinating less or not at all, swelling in your legs, ankles or feet, feeling tired, feeling confused, nausea, pain or pressure in your chest, loss of appetite			X
Behavior and mood changes: agitation, aggressive behavior, hostility, irritability, increased eating, confusion, hallucinations		X	

Bone fracture (broken bone): area around break will be painful and swollen, inability to bear weight or use affected limb			X
Carbohydrate intolerance (inability to digest some carbohydrates due to a lack of some digestive enzymes): diarrhea, bloating, gas	X		
Cerebral edema (swelling in the brain): headache, slow heartrate, irritability, weakness, difficulty talking, drowsiness, fainting, vomiting		X	
Congestive heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue, weakness, swelling in ankles, legs and feet, cough, lack of appetite, nausea, rapid or irregular heartbeat			X
Convulsion: seizure, spasms, shaking, fits			X
Cushing's Syndrome: rounded "moon" face, fragile skin that bruises easily, severe fatigue, muscle weakness, headache, impaired growth in children		X	
Decreased adrenal function: tiredness, weakness, body aches, nausea, vomiting, loss of appetite, low blood pressure, light-headedness, loss of body hair, skin discoloration, weight loss			X
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, withdrawal from social situations, thoughts of death or suicide, feelings of worthlessness, guilt, regret, helplessness or hopelessness, reduced libido (sex drive)	X		
Digestive tract ulcers: heartburn, long-lasting stomach pain, loss of appetite, weight loss, difficulty swallowing, chest pain, nausea		X	
Electrolyte imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		X	
Eye disorders: blurred vision, loss of vision, sensitivity to light, irritation, pain or redness of the eye or eyelids, increased eye pressure, clouding in the lens of the eye, bulging eyes		X	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		X	

Hypertensive crisis (a severe increase in blood pressure): chest pain, headache with confusion and blurred vision, nausea, vomiting, shortness of breath, seizures			X
Hypersensitivity (allergic reaction): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, itchy, watery eyes			X
Hypertrophic cardiomyopathy (thickened heart muscle): breathlessness, chest pain, irregular heartbeat			X
Infection: fever and chills, nausea, vomiting, diarrhea, generally feeling unwell			X
Osteonecrosis: (tiny breaks in a bone leading to eventual collapse): pain in bones, hip, shoulder and knee, limited range of motion in a joint or limb, muscle weakness or wasting, tendon rupture, brittle bones (bones that break easily), broken bones or fractures			X
Osteoporosis (thin, fragile bones): broken bones, pain, back or rib pain that gets worse when standing or walking		X	
Pancreatitis (inflammation of the pancreas): abdominal pain, fever, rapid pulse, nausea, vomiting			X
Skin disorders: acne, excessive hair growth, thinning of skin, rash, bruising, painful red lumps, stretch marks, pain in joints and muscles		X	
Steroid withdrawal syndrome: fever, loss of appetite, nausea, weakness, restlessness, joint pain, skin peeling, low blood pressure and weight loss		X	
Tendon rupture: snapping or popping of a muscle in an arm or leg, severe pain, bruising, inability to use affected arm or leg			X
Tuberculosis (reactivation of lung disease): cough, fever, weight loss			X
Tumor Lysis Syndrome (the rapid death of cancer cells due to the treatment): changes in blood test results (uric acid, potassium, phosphorus, calcium), seizures, lack of urination, darkening of urine, irregular heartbeat			X

Vaginal bleeding changes: increased or decreased menstrual bleeding, spotting, infrequent periods, absence of bleeding	X		
Vertigo (a sense of spinning and dizziness)		X	
Wound complication: a wound that does not heal	X		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15 -30°C. Do not refrigerate. Keep bottle tightly closed.

Keep out of reach and sight of children.

If you want more information about PEDIAPRED:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website www.sanofi.ca, or by calling 1-800-265-7927.

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