

IDAMAN PHARMA PREDNISOLONE TABLET 5MG

Prednisolone (5mg)

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What Idaman Pharma Prednisolone Tablet 5mg is used for

Idaman Pharma Prednisolone Tablet 5mg is used in the treatment of many different conditions. Some of these conditions include: severe allergies, severe or chronic asthma, skin problems, arthritis, inflammatory diseases of the bowel, cancer and "auto-immune" diseases.

It is also used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body. These symptoms can occur in response to injury or can be caused by many different conditions.

How Idaman Pharma Prednisolone Tablet 5mg works

Prednisolone belongs to a group of medicines called corticosteroids which are a synthetic version of a naturally occurring body hormone called cortisol.

Idaman Pharma Prednisolone Tablet 5mg works by entering inflammatory cells and blocking the inflammatory reaction. This medicine is only able to prevent or reduce symptoms of your condition, it does not cure it.

Before you use Idaman Pharma Prednisolone Tablet 5mg

- When you must not use it

Some medicines may increase the effects of Idaman Pharma Prednisolone Tablet 5mg and your doctor may wish to monitor you carefully if you are taking medicines (including some medicines for HIV such as cobicistat).

Do not take Idaman Pharma Prednisolone Tablet 5mg if you have ever had an allergic reaction to:

- prednisolone or prednisone
- any of the ingredients listed at the end of this leaflet.

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.

Do not take it if you have a current serious or uncontrolled infection, including fungal infections.

Do not take Idaman Pharma Prednisolone Tablet 5mg after the expiry date (EXP) printed on the label. It may have no effect at all or an entirely unexpected effect if you take it after the expiry date.

Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so. Do not give this medicine to anyone else.

- Before you start use it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- pheochromocytoma (a tumour of the adrenal gland)
- osteoporosis (weakening of bone) especially in women who have passed menopause

- high blood pressure or heart failure
- diabetes or a history of diabetes in your family
- tuberculosis (a disease of the lungs) or a history of tuberculosis)
- glaucoma (a condition of the eye that affects the vision) or a history of glaucoma in your family
- history of muscle weakness caused by treatment with steroids
- severe liver or kidney problems
- suffered from epilepsy, fits or seizures
- stomach ulcers
- an under active thyroid gland which can cause tiredness and weight gain suffered a recent heart attack
- have ever had blood clots, (for examples, deep vein thrombosis [DVT], or thromboembolism)
- are planning to have a vaccination
- have Cushing's disease (a hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating)
- have Duchenne's muscular dystrophy
- have inflammatory bowel disease such as Crohn's disease
- are undergoing immunosuppression therapy for example in the treatment of cancer
- systemic sclerosis (an autoimmune disorder). Taking daily doses of 15mg or more may increase the risk of a serious complication called scleroderma renal crisis which may cause your blood pressure to increase and reduce urination.

- Taking other medicines

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

Some medicines may interfere with Idaman Pharma Prednisolone Tablet 5mg. These include:

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- antiepileptic drugs such as phenobarbital, carbamazepine, phenytoin and primidone used to treat fits/seizures or epilepsy
- antivirals such as ritonavir which can be used to treat HIV infection
- antibiotics such as erythromycin, rifampicin and rifabutin, which are used to treat some bacterial infections
- thalidomine and aminoglutethimide, used to treat some cancers
- coumarin anticoagulants for example warfarin, which is used to thin the blood
- aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) for example ibuprofen and indometacin, used to treat pain and inflammation due to increased risk of bleeding in the gut or ulcers
- somatotropin or growth hormones
- isoniazid, used to treat tuberculosis
- antifungals such as ketoconazole and amphotericin, which are used to treat fungal infections
- ciclosporin, which is used to treat rheumatic disease, skin complaints, inflammation, or after a transplant
- ritonavir and indinavir, used to treat viral infections
- medicines used to relax muscles during surgery
- cardiac glycosides for example digoxin and related drugs called cardiac glycosides, used to treat heart failure or help strength a weak heart
- salbutamol, formoterol, fenoterol, ritodrine, bambuterol, salmeterol and terbutaline or other sympathomimetic drugs, used to treat breathing difficulties (asthma)
- insulin and other medicines used to treat diabetes
- medicines used to treat high blood pressure
- theophylline, used to treat asthma and chronic obstructive pulmonary disease (COPD)
- female sex hormones - oestrogens, for example in the oral contraceptive pill

- mifepristone, used to induce labour or abortion
- cytotoxic drugs for example methotrexate which is used to treat cancer
- vaccinations
- carbenoxolone which is used for ulcers
- antimuscarinics/anticholinergics
- immunosuppressants which dampen down the activity of the body's immune system
- antacids such as magnesium trisilicate or aluminium hydroxide, used to treat the symptoms of heartburn and indigestion
- acetazolamide which is used in the treatment of glaucoma and epilepsy
- antithyroids such as carbimazole

These medicines may be affected by Idaman Pharma Prednisolone Tablet 5mg or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

How to use Idaman Pharma Prednisolone Tablet 5mg

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Usual Adult Dose: Oral 5 to 60mg a day as a single dose or in divided doses. Dosage requirement are variable and must be individualized on the basis of the disease under treatment and the response of the patient.

Usual Adult Prescribing Limits: Up to 250mg daily.

Usual Children Dose:

Adrenal insufficiency – Oral, 140mcg (0.14mg) per kg of body weight a day in three divided doses.

Other Indications – Oral, 500mcg (0.5mg) to 2mg per kg of body weight a day in three divided doses.

- When to use it

Swallow the tablets whole, with a little water as a single dose in the morning after breakfast unless otherwise directed by the doctor.

Your doctor may want you to follow a low-salt diet and/or a potassium rich diet.

- How long to use it

Continue taking Idaman Pharma Prednisolone Tablet 5mg for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine.

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 all the doctors, dentists and pharmacists treating you that you are taking Idaman Pharma Prednisolone Tablet 5mg.

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Tell your doctor immediately if you became pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

- Things to be careful of

Driving and using machines

There is no evidence that this medicine may affect these abilities as it has not yet been evaluated. However, if the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, Idaman Pharma Prednisolone Tablet 5mg can cause side effects, although not everybody gets them.

Steroids including prednisolone can cause serious mental health problems. These are common in both adults and children.

If you notice any of these problems talk to your doctor straight away:

- feeling depressed, including thinking about suicide
- feeling high (mania) or moods that go up and down
- feeling anxious, having problems sleeping, difficulty in thinking and being confused, or losing memory
- feeling, seeing or hearing things which do not exist (hallucinations)
- having strange and frightening thoughts, changing how you act or having feelings of being alone
- feeling dependant or addicted to this product.

Stop taking Idaman Pharma Prednisolone Tablet 5mg and contact your doctor straight away if the following happens:

- tiredness or sleepless
- increased number of white blood cells

- blood clotting
- nausea and vomiting
- heart problems which can cause shortness of breath
- dizziness or vertigo or headache
- thinning of the skin
- bruising or skin reddening
- skin itching, rash or acne
- slow healing of wounds
- increased sweating
- reduction of growth in babies, children and adolescents
- absence or irregularity of menstrual periods
- weight gain or increase appetite
- increased blood sugar
- vision problems or glaucoma
- worsening of epilepsy
- bulging eyes
- risk of contracting infection is increased
- existing infections can worsen
- previous infections, such as tuberculosis (TB) may be re-activated (flare up)
- muscle pain
- bone fractures or tendon rupture
- stomach ulcers with bleeding or perforation
- bloating
- ulcers in the gullet (oesophagus) which may cause discomfort on swallowing
- abdominal (stomach) pain
- diarrhoea
- high blood pressure (hypertension)
- a change in the levels of some hormones, mineral balance or protein in blood tests
- increased cholesterol or fat levels in blood
- inflammation of the pancreas

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Use in children

Take special care when giving Idaman Pharma Prednisolone Tablet 5mg to children. It should only be given under your doctor's supervision.

Children should not be vaccinated with "live" vaccines against common childhood illnesses while they are taking it, as this may result in severe attacks of these illnesses.

Potentially serious side effects can occur in children and growing teenagers who are taking corticosteroids. Some of these include slowed growth.

Use in elderly

Treatment of elderly patients, particularly if long term, should be planned as more serious consequences of the common side-effects of corticosteroids in old age, especially osteoporosis, diabetes, hypertension, hypokalaemia, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life threatening reactions.

Use in pregnant & lactating mother

Do not take Idaman Pharma Prednisolone Tablet 5mg if you are pregnant or plan to become pregnant. It is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

Do not take it if you are breast feeding or plan to breast feed. It is not recommended for use while breast feeding as it is found in breast milk.

Storage and Disposal of Idaman Pharma Prednisolone Tablet 5mg

- Storage

Store below 30°C in a cool dry place; Protect from light and moisture.

Do not store it or any other medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

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Do not use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month.

Keep it where children cannot reach it.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Clean, dry, round, uniform, flat, bevel edged tablets, scored on one side and white in colour.

- Ingredients:

- Active ingredient(s):

Prednisolone 5mg

- Inactive ingredient(s):

Sodium Starch Glycolate, Purified Water, FD&C Blue No 1, Sodium Benzoate, Corn starch, Lactose, Magnesium Stearate

- MAL Number

MAL19860163AZ

Product Registration Holder & Manufacturer

INSPIRAPHARMA SDN. BHD.

(200401023395)

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