

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Medrol® 4 mg

Tablets

Each tablet contains: methylprednisolone 4 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Medrol is a glucocorticosteroid medicine with anti-allergic and anti-inflammatory action to treat allergic conditions, such as asthma, diverse skin diseases, inflammatory states and arthritis.

Therapeutic group: glucocorticoids.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are **sensitive (allergic)** or suffered from any other type of reaction after having taken the active ingredient or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.
- You suffer from any serious **fungal infection**, such as a serious fungal infection in your lungs or oesophagus (the tube that connects your mouth with your stomach) or any other infection which is not being treated with antibiotic or antiviral medicines.
- You recently had or are about to have any **vaccination**.

If you suffer from a rash or other symptoms of an infection, **tell your doctor immediately.**

Special warnings regarding use of the medicine

Before treatment with Medrol, tell your doctor if you have one of the following conditions.

Your doctor may have to monitor your treatment more closely, alter your dose or give you another medicine:

- **Chickenpox, measles or shingles.** If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them.
- **Worms** (e.g. threadworm).

- Severe **depression** or **manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Medrol or having a family history of these illnesses.
- **Diabetes** (or if there is a family history of diabetes).
- **Fits or seizures.**
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma, or if you have **cataracts.**
- Contact your doctor if you experience **blurred vision or other visual disturbances.**
- **Viral** (e.g. herpes) or **fungal infection** of the eye.
- You recently suffered a **myocardial infarction** (heart attack).
- **Heart problems**, including heart failure.
- **Hypertension** (high blood pressure).
- **Hypothyroidism** (an under-active thyroid).
- **Inflammation of the pancreas** (pancreatitis which causes severe pain in the abdomen and back).
- **Peritonitis** (inflammation of the thin lining (peritoneum) around the gut and stomach).
- **Liver** or **kidney** disease.
- **Scleroderma** (also known as systemic sclerosis, an autoimmune disorder), because the risk of a serious complication called scleroderma renal crisis may be increased. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.
- **Kaposi's sarcoma** (a type of skin cancer).
- **Muscle problems** (pain or weakness) that have happened while taking steroid medicines like Medrol in the past.
- **Myasthenia gravis** (a medical condition that causes tired and weak muscles).
- **Osteoporosis** (brittle bones).
- **Pheochromocytoma** (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys).
- **Skin abscess.**
- **Stomach ulcer** or other serious stomach or intestinal problems.
- **Thrombophlebitis** – vein problems due to thrombosis (blood clots in the veins) resulting in phlebitis (red, swollen and tender veins).
- **Tuberculosis** or if you have suffered tuberculosis in the past.
- **Cushing's disease** (medical condition caused by an excess of cortisol hormone in your body).
- **Brain injury** due to trauma (injury).
- Unusual **stress.**

Tumour lysis syndrome (TLS) can occur after treatment of a fast-growing cancer, such as blood cancers or solid tumours. Symptoms of TLS include muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Drug interactions

If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- **Aminoglutethimide** or **cyclophosphamide** – used for treating cancer.
- **Acetazolamide** – used to treat glaucoma and epilepsy.
- **Anticoagulants** to thin the blood, such as acenocoumarol, phenindione and warfarin.

- **Acetylcholinesterase inhibitors** used to treat myasthenia gravis (a muscle disease), such as distigmine and neostigmine.
- **Antibiotics** (such as isoniazid, erythromycin, clarithromycin and troleandomycin)
- **Antidiabetics** – medicines used to treat high blood sugar levels.
- **Aprepitant, fosaprepitant** – medicines used to prevent vomiting and nausea.
- **Aspirin** and non-steroidal anti-inflammatory medicines (NSAIDs), such as ibuprofen used to treat mild to moderate pain.
- **Barbiturates, carbamazepine, phenytoin and primidone** – used to treat epilepsy.
- **Carbenoxolone and cimetidine** – used to treat heartburn and acid indigestion.
- **Ciclosporin** – used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant.
- **Digoxin** – used to treat heart failure and/or an irregular heartbeat.
- **Diltiazem or mibefradil** – used to treat heart problems or high blood pressure.
- **Ethinylestradiol and norethisterone** – an oral contraceptive.
- **Antivirals** (such as indinavir, ritonavir) **and medicines that enhance the effect (pharmacokinetics) of other medicines** (such as cobicistat) used to treat HIV infections.
- **Ketoconazole or itraconazole** – used to treat fungal infections.
- **Pancuronium or vecuronium** – or other medicines called neuromuscular blocking agents (muscle relaxants) which are used in some surgical procedures.
- **Potassium depleting agents** – such as **diuretics, amphotericin B, xanthenes or beta2 agonists** (e.g. medicines used to treat asthma).
- **Rifampicin and rifabutin** – antibiotics used to treat tuberculosis.
- **Tacrolimus** – used following an organ transplant to prevent rejection of the organ.
- **Vaccines** – tell your doctor or nurse if you have recently had or are about to have any vaccination. You **must not** have "live" vaccines while using this medicine. Other vaccines may be less effective.

If you are taking long term medication(s) (chronic treatment)

If you are being treated for diabetes, high blood pressure or water retention (oedema), tell your doctor as he/she may need to adjust the dose of the medicines used to treat these medical conditions.

Before you have any operation, tell your doctor, dentist or anesthetist that you are taking Medrol.

If you require a test to be carried out by your doctor or in hospital, it is important that you tell the doctor that you are taking Medrol. This medicine can affect the results of some tests.

Using this medicine and food

Swallow the tablets whole with water.

Do not eat grapefruit or drink grapefruit juice while taking this medicine.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine, as it could slow the baby's growth. There is a risk of low birth weight of a baby. This risk can be minimised by taking the lowest effective dose of the corticosteroids.

Cataracts have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

If you are breast-feeding, ask your doctor or pharmacist for advice, as small amounts of corticosteroid medicines may get into breast milk.

Driving and using machines

Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If you are affected by the medicine, do not drive or operate machinery. Caution children against riding a bicycle, playing near a road, and similar activities

Important information about some of this medicine's ingredients

This medicine contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, tell your doctor before starting treatment with this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by your doctor only.

The dose given is individual for every patient based on the type and severity of the disease. Your doctor may prescribe a higher dose at the start of your treatment to bring your condition under control.

Do not exceed the recommended dose.

Do not split the tablets since the resulting halves may not be uniform. There is no information about crushing or chewing the tablets.

Elderly

Your doctor may want to see you more regularly to check how you are getting on with your tablets.

Children and adolescents

Corticosteroids can affect growth in children and adolescents so your doctor will prescribe the lowest dose that will be effective to treat your child. Your doctor may tell you to give your child this medicine intermittently (every other day).

If you have accidentally taken a higher dosage

It is important that you do not take more tablets than what you were instructed by your doctor. If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine

If you forget to take this medicine, wait and take the next dose at the regular time. Do not take a dose to make up for the forgotten one but tell your doctor or pharmacist what had happened.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Stopping/reducing treatment with the medicine

Your doctor will decide when it is time to stop the treatment.

Do not stop the treatment suddenly, especially if you:

- have taken more than 6 mg Medrol daily for more than 3 weeks
- have been given high doses of Medrol (more than 32 mg daily) even if it was only for 3 weeks or less.
- have already had a course of treatment with corticosteroid tablets or injections in the last year.
- already had problems with your adrenal gland before you started this treatment.
- take repeat doses in the evening.

You will need to come off Medrol slowly to avoid **withdrawal symptoms**. Withdrawal symptoms may include itchy skin, fever, muscle and joint pain, runny nose, sticky eyes, loss of appetite, nausea, vomiting, headache, feeling tired, peeling skin and weight loss.

If your symptoms seem to return or get worse as your dose of Medrol is reduced, tell your doctor immediately.

Mental problems while taking Medrol

Mental problems can happen while taking steroids like Medrol (see section 4).

- These disorders can be serious.
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or if the medicine is stopped. However, if the problems do happen, they might need treatment.

Talk to a doctor if you (or the patient taking this medicine) shows any signs of mental disorders. This is particularly important if you are depressed or might be thinking about suicide. In a few cases, mental problems happened when doses were lowered or stopped.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Medrol may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

In certain medical conditions medicines like Medrol (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms, seek immediate medical attention. Your doctor will then decide whether you should continue taking your medicine:

Common side effects (may occur in up to 1 in 10 people):

- **Burst or bleeding ulcer**, symptoms of which are stomach pain (especially if it seems to spread to your back), bleeding from the back passage, black or bloodstained stools and/or vomiting blood.
- **Infections**. This medicine can hide or change the signs and symptoms of some infections, or reduce your resistance to the infection, so that they are hard to diagnose at an early stage.

Symptoms might include a raised temperature and feeling unwell. Symptoms of a flare up of a previous tuberculosis infection could be coughing blood or pain in the chest. Medrol may also make you more likely to develop a severe infection.

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- **Allergic reactions**, such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare but can be serious.
- **Pancreatitis**, stomach pain spreading to your back, occasionally accompanied by vomiting, shock and loss of consciousness.
- **Pulmonary embolus** (blood clots in the lungs). Symptoms include sudden sharp chest pain, breathlessness and coughing up blood.
- **Raised pressure within the skull** in children (pseudotumour cerebri) symptoms of which are headaches with vomiting, lack of energy and drowsiness. This side effect usually occurs after treatment is stopped.
- **Thrombophlebitis** (blood clots or thrombosis in a leg vein), symptoms of which include swollen, red, painful and tender veins.

If you experience any of the following side effects, or notice any other unusual effects not mentioned in this leaflet, tell your doctor straight away:

Blood, heart and circulation

Common side effects (may occur in up to 1 in 10 people):

High blood pressure. Symptoms of which are headaches or generally feeling unwell.

Side effects of unknown frequency (frequency cannot be estimated from the available data):

Problems with the contractions of the heart (heart failure) – symptoms of which are swollen ankles, difficulty in breathing and palpitations or irregular beating of the heart, irregular or very fast or slow pulse; increased numbers of white blood cells (leukocytosis); low blood pressure.

Body water and salts

Common side effects (may occur in up to 1 in 10 people):

Swelling and high blood pressure caused by increased levels of water and salt content; cramps and spasms due to the loss of potassium from the body. In rare cases, this can lead to congestive heart failure (when the heart cannot pump properly).

Side effects of unknown frequency (frequency cannot be estimated from the available data):

Increased blood urea levels.

Digestive system

Side effects of unknown frequency (frequency cannot be estimated from the available data):

Nausea or vomiting; ulcers, inflammation or thrush in the oesophagus (the tube that connects the mouth with the stomach), which can cause discomfort on swallowing; indigestion; peritonitis (inflammation of the thin lining around the gut and stomach); bloated stomach; abdominal pain; diarrhoea; persistent hiccups, especially when high doses are taken.

Eyes

Common side effects (may occur in up to 1 in 10 people):

Damage to the optic nerve or cataracts (indicated by failing eyesight).

Rare side effects (may occur in up to 1 in 1,000 people):
Blurred vision.

Side effects of unknown frequency (frequency cannot be estimated from the available data):
Glaucoma (raised pressure within the eye that causes pain in the eyes and headaches); swollen optic nerve (papilloedema, indicated by sight disturbance); thinning of the clear part at the front of the eye (cornea) or of the white part of the eye (sclera); worsening of viral or fungal eye infections; protruding of the eyeball (exophthalmos); blurred or distorted vision (due to a disease called chorioretinopathy).

Hepatobiliary disorders

Side effects of unknown frequency (frequency cannot be estimated from the available data):
Increase of liver enzymes.

Hormone and metabolic system

Common side effects (may occur in up to 1 in 10 people):
Slowing of normal growth in infants, children and adolescents which may be permanent.
Round or moon-shaped face

Side effects of unknown frequency (frequency cannot be estimated from the available data):
Irregular or no periods in women; increased hair on the body and face in women (hirsutism); increased appetite and weight gain; abnormal blood level of lipids (e.g. cholesterol and/or fat); diabetes or worsening of existing diabetes; prolonged therapy can lead to lower levels of some hormones which in turn can cause low blood pressure and dizziness. This effect may persist for months; The amount of certain chemicals (enzymes) called alanine transaminase, aspartate transaminase and alkaline phosphatase that help the body digest drugs and other substances in the body may be raised after treatment with corticosteroids. The change is usually small and the enzyme levels return to normal after the medicine has cleared naturally from the body. You will not notice any symptoms if this happens but it will show up in blood tests; accumulation of fat tissue on localised parts of the body, manifesting as different presentations for example back pain or weakness (due to epidural lipomatosis).

Immune system

Side effects of unknown frequency (frequency cannot be estimated from the available data):
Increased susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis.

Muscles and bones

Common side effects (may occur in up to 1 in 10 people):
Muscle weakness and wasting.

Side effects of unknown frequency (frequency cannot be estimated from the available data):
Brittle bones (bones that tend to break easily); broken bones or fractures; breakdown of bone due to poor circulation of blood, this causes pain in the hip; joint pain or joint problems; torn muscle tendons causing pain and/or swelling; muscle pain, cramps or spasms.

Nervous system

Steroids, including methylprednisolone, can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like methylprednisolone.

Depression, including thinking about suicide; feeling high (mania) or moods that go up and down; anxiety, having problems sleeping, difficulty in thinking or being confused and losing memory; feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

Side effects of unknown frequency (frequency cannot be estimated from the available data): Irritability, fits, a feeling of dizziness or 'spinning', headache.

Skin

Common side effects (may occur in up to 1 in 10 people): Acne; poor wound healing; thinning of skin.

Side effects of unknown frequency (frequency cannot be estimated from the available data): Stretch marks; bruising; sweating, itchy skin; rash or redness of skin; hives (red, itchy, swollen skin); dilation of small blood vessels on the surface of the skin (red spider veins); red, brown or purple pinpoint round spots; brown/purple/red raised patches on the skin or inside the mouth (Kaposi's sarcoma).

Vascular disorders

Side effects of unknown frequency (frequency cannot be estimated from the available data): Increased clotting of the blood.

Other side effects

Side effects of unknown frequency (frequency cannot be estimated from the available data): Feeling unwell; feeling tired; accumulation of fluid causing swelling in the body, especially in the lower limbs; suppression of reactions to skin tests.

It is important if you are to have a blood test that you tell the doctor or nurse that you have been given treatment with Medrol.

If you experience any of the side effects listed above, tell your doctor straight away.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet or if a change has occurred in your general wellbeing, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link :<https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

lactose monohydrate, maize starch, sucrose, calcium stearate

What the medicine looks like and contents of the pack:

White, semi-oval, elliptical and double scored tablets on one side, and with 'MEDROL 4' imprinted on the other side.

The package contains 30 tablets in a tray pack (blister).

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Registration number of the medicine in the Ministry of Health's National Drug Registry:

024-65-22188

Revised in 06/2023 according to MOH guidelines.