PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

MEDROL® 4 mg

Tablets

Each tablet contains:
Methylprednisolone 4mg
For the list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine if you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medicial condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?
Medrol® is a glucocorticosteroid medicine with anti-allergic and anti-inflammatory activity, for the treatment of allergic conditions such as: asthma, a variety of skin diseases, inflammatory conditions and arthritis.
Therapeutic group:
Glucocorticoids.

2. BEFORE USING THE MEDICINE
MD not use the medicine if:

X You are sensitive (allergic), or have suffered from another reaction after being given the active substance or any other ingredients contained in the medicine (listed in section 6). An allergic reaction may cause skin rash or redness, swelling of the face or lips or shortness of breath.
X You are suffering from a serious fungal infection in your lungs or esophagus (the tube that connects the mouth with the stomach) or any other infection that is not treated with antibiotic or antiviral medicines.

X You have recently had, or are about to have any type of vaccination.

If you are suffering from a rash or other symptoms of an infection, inform the doctor imay monitor your treatment more closely, adjust your dosage or prescribe a different medicine for you:

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 then.

Worms (e.g., threadworm).

Severe depression or manic depression while taking strend like Medrol®, or having a family history of these illnesses.

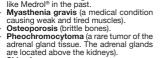
Diabetes (or if there is a family history of diabetes).

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Fits or seizures.
Glaucoma (high fluid pressure in the eye) or if there is a family history of glaucoma, or if you suffer from a cataract.
Contact your doctor if you experience blurred vision or other visual disturbances.
Viral infection (e.g. herpes) or fungal infection of the eye.
You recently suffered a myocardial infarction (heart attack).
Heart function problems, including heart failure.

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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 surrounding the intestine and stomach [peritoneum]). Liver or kidney disease. Scleroderma (connective tissue/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) have occurred while taking steroid medicines like Medrole in the past.
- Myasthenia gravis (a medical condition causing weak and tired muscles).
- Osteoprosis (brittle bones).
- Pheochromocytoma (a rare tumor of the 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 venous thrombosis (blood clots in the veins) resulting in phlebitis (red, swollen, tender and painful veins).
- Tuberculosis (TB) or if you have suffered from tuberculosis in the past.
- Cushing's disease (a medical condition caused by an excess of cortisol hormone in the body).
- Brain injury due to trauma (injury).
- Unusual stress.
- Drug interactions:
- If you are taking or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist.
- Especially if you are taking:
- Aminoglutethimide or cyclophosphamide—used for treating cancer.
- Acetazolamide — used to treat glaucoma and epilepsy.
- Anticoagulants — used to 'thin' the blood such as acenocoumarol, phenindinne and







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Acetylcholinosters

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Acetylcholinesterase inhibitors such as distigmine and neostigmine – used to treat myasthenia gravis (a muscle disease).

Antibiotics (such as isoniazid, erythromycin, clarithromycin and troleandomycin).

Antidiabetics – medicines used to treat high blood sugar levels.

Aprepitant, fosaprepitant – medicines used to prevent nausea and vomiting.

Aspirin and non-steroidal anti-inflammatory drugs (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 theartburn and gastric hyperacidity disturbances.

ist year. already had problems with you hal glands before starting the curre adrenal glands before starting the content treatment.

You took repeat doses in the evening. Discontinuation of Medrol® treatment will be performed gradually to avoid withdrawal symptoms. Withdrawal symptoms may include: itchy skin, fever, muscle and joint pains, runny nose, sticky eyes, loss of appetite, nausea, vomiting, headache, fatigue, peeling skin and weight loss. If the symptoms seem

If you have further questions regarding use of the medicine, consult a 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 the list of side effects. You may not suffer from any of them.

In certain medical conditions, use of medicines like Medrol® (steroids), should not be stopped abruptly. If you suffer from any of the following symptoms, refer to a doctor immediately. Your doctor will decide whether you should continue taking this medicine:

Common side effects (effects that occur in 1-10 out of 100 users):

Perforation or bleeding ulcer, symptoms may include stomach pain (especially if it seems as if the pain spreads to your back), bleeding from the rectum, black or bloody stools and/or vomitting blood.

Infections. This medicine can mask 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 fever and feeling unwell. Symptoms of a flare up of a previous tuberculosis (TB) infection could include coughing up blood or pain in the chest. Medrol® may also lead to an increased risk of developing a severe infection. infection could include coughing up blood or pain in the chest. Medrol® may also lead to an increased risk of developing a severe infection.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

• Allergic reactions, such as skin rash, swelling of the face or wheezing and difficulty breathing. This side effect is rare, but can be serious.

• Pancreatitis, stomach pain spreading to the back, sometimes accompanied by vomiting, shock and loss of consciousness.

• Pulmonary embolus (blood clots in the lungs); the symptoms include sudden sharp chest pain, breathlessness and coughing up blood.

• Raised pressure within the skull of children (pseudotumor cerebri); the symptoms of this condition are: headaches with vomiting, lack of energy and sleepiness. This side effect usually occurs after treatment is stopped.

• Thrombophlebitis (blood clots or thrombosis in a leg vein); the symptoms 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 immediately:

Blood, heart and blood circulation

Common side effects (effects that occur in 1-10 out of 100 users):

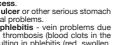
High blood pressure, symptoms of which are headaches, or generally feeling unwell.

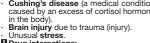
Side effects of unknown frequency (effects whose frequency has not yet been determined):

Heart contraction disturbances (heart failure)-symptoms of which are swollen ankles, difficulty in breathing and palpitations or irregular heart beating, irregular or very fast or slow pulse; lncreased number of white blood cells (leukocytosis); Low blood pressure.

Body water and salts

Common side effects (effects that occur in 1-10 out of 100 users):
Swelling and high blood pressure, due to increased levels of water and salt; Cramps and spasms, due to the loss of potassium from the body. In rare cases, this can lead to heart failure (when the heart cannot pump properly).
Side effects of unknown frequency (effects whose frequency has not yet been determined):
Increased blood urea levels.
Digestive system
Side effects of unknown frequency (effects whose frequency has not yet been determined):
Nausea (feeling sick) or vomiting (being sick); Ulcers, inflammation or thrush in the esophagus (the tube that connects the mouth with the stomach), which can cause discomfort on swallowing; Indigestion; Peritonitis (inflammation of the thin layer around the intestine and stomach [peritoneum]): Bloated stomach; Abdominal pain; Diarrhea; Persistent hiccups, especially when high dosages are taken.
Eyes





to treat heartburn and gastric hyperacidity disturbances.

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.

Dilitiazem or mibefradil – used to treat heart problems or high blood pressure.

Ethinylestradiol and norethisterone – contraceptives.

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nedicine
our doctor will decide when it is time to top the treatment.
It is not taking the treatment suddenly, specially in the following situations:
You took more than 6 mg Medrol® daily, for more than 3 weeks.
You received high doses of Medrol® (more than 32 mg daily), even if it was for 3 weeks or less.
You have already had a course of treatment with corticosteroid tablets or injections in the last year.
You already had problems with was for a daready had problems with was formed the state of the state o

Eyes

Common side effects (effects that occur in 1-10 out of 100 users):

Damage to the optic nerve or cataract (indicated by blurred vision).

Rare side effects (effects that occur in 1-10 out of 10,000 users):

Blurred vision. Blurred vision.

Side effects of unknown frequency
(effects whose frequency has not yet been
determined):

(effects whose frequency has not yet been determined):
Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches);
Swollen optic nerve (papilledema, 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; Protrusion of the eye (exophthalmos); Blurred or distorted vision (due to a disease called chorioretinopathy). Hepatobiliary disorders
Side effects of unknown frequency (effects whose frequency has not yet been determined):
Increase in liver enzyme levels.
Hormone and metabolic system
Common side effects (effects that occur in 1-10 out of 100 users);
Slowing of normal growth in infants, children and adolescents, which may be irreversible; Round or moon-shaped face (Cushingoid facies).

and adolescents, which may be irreversible; Round or moon-shaped face (Cushingoid facies). Side effects of unknown frequency (effects whose frequency has not yet been determined): Menstrual disturbances or no periods in women; Increased hairiness on the body or 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 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 rise after treatment with corticosteroids. The change is usually small and the enzyme levels return to normal after natural clearance of the medicine from the body. This effect has no symptoms, but it will show up in blood tests; Accumulation of fat tissue in certain parts of the body, manifests as different effects, such as back pain or weakness (due to epidural lipomatosis). Immune system

Side effects of unknown frequency (effects whose frequency has not yet been determined); Increased susceptibility to infections which may mask or change normal reactions to

Side effects of unknown frequency (effects whose frequency has not yet been determined): Increased susceptibility to infections which may mask or change normal reactions to skin tests, such as for tuberculosis.

Muscles and bones

Common side effects (effects that occur in 1-10 out of 100 users):

Muscle weakness and wasting.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

Brittle bones (bones that break easily); Fractured and broken bones; Breakdown of bone due to poor circulation of blood, that 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 disturbances. The effects are common in both adults and children. They can affect about 5 in every 100 patients taking medicines such as methylprednisolone.

Depression, including suicidal thoughts; Feeling high (mania) or mood changes (up and down); Anxiety, sleeping disturbances, difficulty in thinking or confusion and impaired memory; Feeling, seeing or hearing things which do not exist. Strange and frightening thoughts, behavioral changes or feelings of being alone.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

Irritability; Fits; Dizziness or a feeling of dizziness; Headache.

Skin

Common side effects (effects that occur in 1-10 out of 100 users):

Skin
Common side effects (effects that occur in
1-10 out of 100 users):
Acne; Poor wound healing; Thinning of skin.
Side effects of unknown frequency
(effects whose frequency has not yet been
determined):
Stretch marks; Bruises; Sweating; Itchy
skin; Rash or redness of skin; Hives (skin
redness, itchiness and swelling); Dilation of
small blood vessels on the surface of the
skin (red spider veins); Red, brown or purple,
pin point, round spots; Brown/purple/red
raised patches on the skin or inside the
mouth (Kaposi's sarcoma).
Vascular system disorders
Side effects of unknown frequency
(effects whose frequency has not yet been
determined):
Increased clotting of the blood.
Other side effects
Side effects of unknown frequency
(effects whose frequency has not yet been
determined):
Feeling unwell; Feeling tired; Accumulation of
fluid causing swelling in the body, especially
the lower limbs; Suppression of reactions
to skin tests.
If you have to have a blood test, it is
important that you tell the doctor or nurse
that you are being treated with Medrol®.

If you experience any of the side effects
listed above, tell your doctor immediately.
If a side effect occurs, if one of the side
effects worsens, when you suffer from a
side effect not mentioned in the leaflet, or if
there is a change in your general wellbeing,
consult with the doctor.
Side effects can be reported to the Ministry of
Health by clicking on the link "Reporting Side
Effects of Drug Treatment" found on the Ministry
of Health homepage (www.health.gov.il)
that directs you to the online form for reporting
side effects, or by entering the link:
https://forms.gov.il/globaldata/eptsequence
/ getsequence.aspx?formType=AdversEffec
tiMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE
STORED?
Avoid poisoning! This medicine, and any
other medicine, should be kept in a safe
place out of the reach and sight of children
and/or infants in order to avoid poisoning.
Do not induce vomiting unless explicitly
instructed to do so by the doctor.
Do not use the medicine after the

that month.

Store below 25°C.

FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, maize starch, sucrose, calcium stearate. Each tablet contains 80

Each tablet contains 80 mg lactose monohydrate and 1.5 mg sucrose. What the medicine looks like and the contents of the package: The tablets are white, half-oval, elliptical, with two score lines on one side and 'Medrol 4' marked on the other. The package contains 30 tablets in a blister. two score lines on one side and 'Medrol 4' marked on the other. The package contains 30 tablets in a blister. Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzellya Pituach, 46725. Manufacturer and address: Pfizer Italia S.R.L., Ascoli Piceno, Italy. Registration number of the medicine in the National Drug Registry of the Ministry of Health: 024-65-22188 This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved in June 2017 and updated according to the guidelines of the Ministry of Health in July 2019.

to return or get worse during Medrol® dosage reduction, tell your doctor immediately. Mental disturbances while taking Medrol® Mental disturbances can occur while taking steroids like Medrol® (see section 4).

• These disturbances can be serious.

• Usually, they start within a few days or weeks of starting the medicine.

• Their chance of occurring is higher when taking high dosages.

• These disturbances usually resolve when the dosage is lowered or when you stop taking the medicine. However, if the disturbances occur, they might need treatment.

Consult with the doctor if you (or the patient taking the medicine) suffer from symptoms of mental disturbances. This is particularly important if you suffer from depression or from suicidal thoughts. In a few cases, mental problems have occurred when the dosage was being lowered or stopped.

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

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.