MEDROL®

Methylprednisolone

4 mg Tablets

16 mg Tablets

Reference Market: Italy

Common Export Pack

PACKAGE LEAFLET

Package leaflet: Information for the user

MEDROL® 4 mg tablets
MEDROL® 16 mg tablets

Methylprednisolone

Read all of this leaflet carefully before you and/or your child receive this medicine because it contains important information for you and/or your child.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, the doctor treating your child or your pharmacist.
- This medicine has been prescribed for you and/or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you and/or your child get any side effects, talk to your doctor, the doctor treating your child or your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Medrol is and what it is used for

Medrol contains the active substance methylprednisolone. Methylprednisolone belongs to a group of medicines called corticosteroids. Corticosteroids are substances produced naturally by the body, and are important for many bodily functions.

Medrol is used **to treat**:
- diseases in which the body is unable to produce a sufficient quantity of natural corticosteroids, due to, for example **problems with the adrenal glands**, such as adrenal insufficiency;
- **diseases of the joints** (e.g. rheumatoid arthritis or psoriatic arthritis);
- **skin diseases** (e.g. pemphigus and serious psoriasis);
- **allergies** (e.g. allergic rhinitis and bronchial asthma);
- **eye diseases** (e.g. diffuse posterior uveitis, optical neuritis, iritis and iridocyclitis);
- **lung diseases** (e.g. sarcoidosis);
- **blood diseases** (e.g. leukaemia);
- **intestinal diseases** (e.g. segmental enteritis and ulcerative colitis);
- **brain diseases** (e.g. tubercular meningitis).

Medrol may be prescribed to treat diseases other than those listed above.
Talk to your doctor if you are not sure why this medicine has been prescribed for you or your child.

2. What you need to know before you take Medrol/give Medrol to your child

Do not use/give your child Medrol if you and/or your child:
- is/are **allergic** to methylprednisolone or to any of the other ingredients of this medicine (listed in section 6);
- if you have an **infection** caused by **fungi** that has spread to certain organs or to the whole body.

You or your child must not have "live" or "attenuated live" **vaccines** while being treated with Medrol.

Warnings and precautions
Talk to your doctor, nurse or pharmacist **BEFORE** you or your child use/receive this medicine if you or your child:

- have or have ever had **tuberculosis**;
- are in a particularly **stressful** situation. In this case, your doctor will prescribe a higher dose of this medicine for you or your child;
- have **Cushing's disease**, a condition caused by an excess of natural corticosteroids in the body. Medrol may aggravate your or your child's condition;
- if you have lower than normal thyroid function (**hypothyroidism**). In this case, the doses of Medrol should be reduced;
- have **diabetes**;
- have **myasthenia gravis**, a condition causing tired and weak muscles, or if you or child have a **procedure with general anaesthesia** that calls for the use of medicines that block the muscles (e.g. pancuronium). In this case, the risk that Medrol will cause muscle problems is greater;
- suffer from **seizures**
- have an **eye infection** caused by the *Herpes simplex* virus;
- have high blood pressure (**hypertension**);
- have high levels of fat in the blood (**dyslipidaemia**);
- have heart problems (**heart failure**);
- have or are predisposed to developing blood clots in your veins;
- have a **stomach ulcer** or other serious problems in the stomach or intestines;
- have **cirrhosis of the liver**, a liver disease;
- have **kidney problems**;
- have **scleroderma** (also known as systemic sclerosis, an autoimmune disorder), because the risk of a serious complication called scleroderma renal crisis may be increased;
- have a **brain injury** caused by trauma;
- are being treated with **non-steroidal anti-inflammatory drugs** (e.g. acetylsalicylic acid) (see section "Other medicines and Medrol);
- you have had to undergo **skin sensitivity tests**;
- have a type of cancer called **pheochromocytoma**;
- suffer from peritonitis or other gastrointestinal diseases, since glucocorticoid therapy may mask symptoms, such as perforation, obstruction or pancreatitis.

Speak to your doctor or the doctor that is treating your child if any of the following conditions appears or worsens **DURING** treatment with this medicine (also see section 4 "Possible side effects"):

- **infections**. This medicine can increase susceptibility to infections or make ongoing infections worse. For example, chickenpox and measles can become more serious, and sometimes fatal;
- **Kaposi's sarcoma**, a skin tumour. In this case, **stop** treatment with Medrol;
- **severe allergic reactions**;
- **swelling** in different parts of the body, especially the legs and calves, or alterations in normal levels of **mineral salts in the blood**;
- onset or worsening of **mental disorders** (e.g. depression). Tell the people you live with about the possible effects of this medicine;
- **eye problems**;
- severe **inflammation of the pancreas**;
- **osteoporosis** (brittle bones);
- **accumulation of fat** that compresses the spinal cord;
- **hepatobiliary diseases** (reversible after interruption)

- blurred vision or other visual disturbances

You or your child must not have "live" or "attenuated live" **vaccines** while being treated with Medrol (see paragraph “Do not take Medrol/give Medrol to your child”). You may instead receive vaccinations with **dead** or **inactivated vaccines**, even if the efficacy of these vaccines may be decreased.

Athletes
Athletes: the use of the medicine without therapeutic need constitutes doping and may cause positive anti-doping tests.

Newborns and infants
Treatment with Medrol for long periods of time or at high doses may cause delayed growth, increased intracranial pressure and inflammation of the pancreas in newborns and children.

Elderly
If you are elderly, treatment with Medrol for long periods of time may increase the risk of developing osteoporosis, excessive fluid retention in the body and increased blood pressure. Your doctor will assess your condition and give you this medicine with caution.

Other medicines and Medrol
Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicine, including medicines without a prescription. Some medicines may increase the effects of Medrol and your doctor may want to keep you under close observation if you are taking these medicines.

The following medicines can affect the activity of Medrol or Medrol may affect the efficacy and/or toxicity of the following medicines:
- **isoniazid**, **troleandomycin, clarithromycin** and **erythromycin** (antibiotics);
- **rifampicin** (antibiotic used to treat tuberculosis);
- **phenobarbital**, **phenytoin, carbamazepine** (medicines for seizures) and other **barbiturates** (calming medicines that induce sleep);
- **aprepitant** and **fosaprepitant** (medicines for vomiting);
- **itraconazole**, **ketoconazole** and **amphotericin B** (medicines to treat fungal infections);
- **medicines to treat HIV,** such as **indinavir, ritonavir** and **cobicistat** (medicines to combat the HIV virus);
- **aminoglutethimide** (medicine for excessive production of natural corticosteroids);
- **diltiazem** (medicine used to treat cardiac problems or high blood pressure);
- **ethinyl estradiol/norethindrone** (hormones used in combination with oral contraceptives);
- **cyclosporine**, **cyclophosphamide** and **tacrolimus**, medicines to prevent rejection after organ transplant and against autoimmune diseases;
- **oral anticoagulants**, medicines used to thin the blood;
- **neuromuscular blocking agents** (medicines that cause the muscles to relax);
- **anticholinesterases** (medicines for muscle diseases such as myasthenia gravis and Alzheimer's disease);
- **antidiabetics** (medicines for diabetes);
- **aspirin** (acetylsalicylic acid);
- **diuretics** (medicines that increase the production of urine;
- **xanthine** and **beta-2-agonists** (medicines to treat asthma).

Medrol with drink

You or your child should **not drink grapefruit juice** during treatment with Medrol because the efficacy and toxicity of this medicine may increase.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, or if you are breastfeeding, ask your doctor or pharmacist for advice before using/you are administered this medicine.

Pregnancy
If you use this medicine during pregnancy, especially for a long period, your child may present with side effects at birth. Therefore, if you are pregnant, the doctor will prescribe Medrol only if strictly necessary

Breast-feeding
Medrol passes into the breast milk and this could cause undesirable effects in the baby. If you are pregnant or breast-feeding, your doctor will prescribe you Medrol only if strictly necessary.

Fertility
On the basis of the information currently available, this medicine may reduce fertility.

Driving and using machines
Do not drive vehicles or use machines if, during treatment with Medrol, you have headaches, vertigo, blurry vision and fatigue.

Medrol contains lactose and sucrose
Medrol contains lactose and sucrose, two types of sugars. If you have been told by your doctor that you have an intolerance to some sugars, tell your doctor before taking this medicine.

This medicine contains lactose produced from cow's milk and may contain traces of milk protein. If your doctor diagnosed or suspected you have an allergy to cow's milk protein, contact him before taking this medicine.

3. How to take Medrol/give Medrol to your child

Always take/give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The initial recommended dose varies from 4 mg to 48 mg per day. Based on your conditions or the conditions of your child and the type of disease, the doctor will recommend the dose, how many times per day to take/give your child the medicine and the duration of treatment with Medrol.
If the doctor is satisfied with the improvement of the disease, he/she will consider reducing the dose gradually, until the minimum most appropriate dose is achieved (maintenance dose).

Swallow the tablets whole with a drink of water. Do not chew or crush the tablets.

If you take more Medrol than you should
It is important that you do not take more tablets than those prescribed. If you or your child accidentally take too high a dose of Medrol, seek medical attention straight away.

If you forget to take Medrol
Do not take a dose to make up for the forgotten dose. If you forget a dose, consult your doctor.

If you stop your treatment with Medrol

You or your child **should not stop taking Medrol suddenly**. Medrol may cause a decrease in the functioning of the adrenal glands, which produce natural corticosteroids, and a sudden interruption may lead to death.
Moreover, in the event of the sudden interruption of treatment with Medrol, you or your child may develop **withdrawal symptoms** such as: anorexia, nausea, vomiting, drowsiness, headache, fever muscle and joint pain, desquamation of the skin, weight loss, decrease in blood pressure and mental disorders.
If the medicine is to be stopped, the dose must be reduced gradually. Your doctor will advise you on the right way to do this.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor if you have any of the following side effects:

Not known (cannot be estimated from the available data):
- infections, including infections that appear when the body's immune defences are very low
- increased number of white blood cells
- inflammation of the abdomen (peritonitis)
- hypersensitivity to the medicine
- serious allergic reaction, e.g. swelling of the face, tongue and throat with difficulty swallowing and breathing (angio-oedema)
- round or moon face (Cushingoid appearance)
- reduced secretion of hormones by the pituitary gland (a gland at the base of the brain)
- withdrawal syndrome from the treatment (see section 3 “If you stop your treatment with Medrol”)
- disorders due to interference in the balance between the hormones produced by the pituitary gland and those produced by the adrenal glands
- loss or increase in body's acidic substances
- fluid and sodium retention in the body
- increased levels of fat in the blood
- decrease in potassium levels in the blood
- glucose metabolism disorder (altered tolerance to glucose)
- worsening of existing diabetes
- accumulation of fatty tissue in certain parts of the body
- increased appetite and weight gain
- mental disturbances, such as: emotional disorders (depression, euphoric mood, affective disorder and drug addiction; suicidal ideation), manic behaviour, delirium, hallucinations, schizophrenia, disturbed thoughts, personality change, confusion, anxiety, mood swings, abnormal behaviour, insomnia, irritability
- accumulation of fat that compresses the spinal cord
- increased pressure in the fluid in the skull
- seizures
- memory difficulties
- thought disorders that affect awareness of reality
- dizziness
- vertigo
- headache
- cataracts
- bulging eyes

- increased intra-ocular pressure (glaucoma)
- decreased vision in the central field of vision
- disease of the retina and choroid membrane
- increase or decrease in blood pressure
- increased clotting of the blood
- hiccups
- formation of blood clots in the veins and lungs
- disorders of the stomach and intestine, such as stomach ulcers with possible bleeding and perforation
- abdominal distension and pain
- diarrhoea, nausea
- difficulty digesting
- stomach bleeding
- perforation of the intestine
- inflammation of the oesophagus, with or without ulcer
- inflammation of the pancreas
- bruising
- reddening of the skin, skin rash
- increase in hair growth
- excessive sweating
- appearance of small red spots or thin purple stripes on the skin
- itching
- hives
- acne
- skin atrophy
- alteration in water levels and mineral salts. This condition may rarely cause high blood pressure and heart problems (heart failure)
- muscular weakness
- muscle and joint pain, muscle diseases, reduced muscle mass
- bone fragility (osteoporosis), bone tissue death and loss
- joint rupture (especially in the feet) that causes pain and/or swelling
- vertebral fractures (due to trauma or spontaneous), tendon rupture, especially the Achilles tendon
- irregular menstruation
- delayed wound healing
- fatigue
- malaise
- changes in laboratory tests to assess the functioning of the liver
- increased liver enzymes
- increase of calcium levels in the urine
- reduced response to skin tests
- blood urea increased
- tendency of the body to lose more protein than that which is introduced with the diet (metabolic acidosis)
- Blurred vision

Additional effects in children

Frequency not known (cannot be estimated from the available data):
- delayed growth
- changes in growth

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Medrol

Store below 30°C.

Store this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and bottle after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Medrol contains
The active substance is methylprednisolone.

Each 4 mg tablet of Medrol contains 4 mg of methylprednisolone.
The other ingredients are **lactose monohydrate**, **sucrose** (see paragraph 2 "Medrol contains lactose and sucrose"), maize starch, calcium stearate.

Each 16 mg tablet of Medrol contains 16 mg of methylprednisolone.
The other ingredients are **lactose monohydrate**, **sucrose** (see paragraph 2 "Medrol contains lactose and sucrose), liquid paraffin, calcium stearate, maize starch.

What Medrol looks like and contents of the pack

Medrol 4 mg tablets are half oval, elliptical, white tablets, debossed "Medrol 4" one side and double scored on the other side. The tablets are available in high-density polyethylene (HDPE) bottle containing 10, 30 tablets or in transparent and aluminium PVC blister packs of 30 tablets.

Medrol 16 mg tablets are semi-oval, oval, whitish tablets with one side marked "Medrol 16" and cross-scored on the other side. The tablets are available in transparent and aluminium PVC blister packs of 20 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

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Pfizer Italia S.r.l.
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