Package leaflet: Information for the user

Methylprednisolon Eurogenerics 4 mg tabletten
Methylprednisolon Eurogenerics 16 mg tabletten
Methylprednisolone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you 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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Methylprednisolon Eurogenerics is and what it is used for
2. What you need to know before you take Methylprednisolon Eurogenerics
3. How to take Methylprednisolon Eurogenerics
4. Possible side effects
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6. Contents of the pack and other information

1. What Methylprednisolon Eurogenerics is and what it is used for

Methylprednisolon Eurogenerics contains methylprednisolone. Methylprednisolone belongs to a group of medicines called corticosteroids.

Methylprednisolone inhibits local signs of inflammation (fever, swelling, pain, redness) and hypersensitivity reactions. It also acts on several organs and metabolic processes.
Therefore, it is used to treat a wide range of conditions, including:
- rheumatic conditions of a variety of origins;
- allergic conditions: including hay fever, asthma, drug allergies;
- skin conditions;
- eye conditions of allergic or inflammatory origin;
- certain types of inflammation of the digestive tract;
- certain disorders of the airways;
- certain severe blood diseases;
- abnormal adrenal function;
- organ transplantation.

2. What you need to know before you take Methylprednisolon Eurogenerics

Do not take Methylprednisolon Eurogenerics:
- if you are allergic to methylprednisolone or any of the other ingredients of this medicine (listed in section 6)
- if you have a viral or fungal infection
- if you have a gastric or duodenal ulcer
- if you have a tropical worm infection
- if you are receiving certain vaccines or did receive them in the past 3 months.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Name]:

- Regular medical supervision is necessary if:
  - you belong to one of the special risk groups (see section 4).
  - you have had or are currently suffering from tuberculosis, a heart condition or infections.
  - you have had or are currently suffering from digestive disorders, gastrointestinal disorders (ulcer, colitis, etc.). Treatment with glucocorticoids may mask inflammation of the peritoneum (peritonitis), or other signs or symptoms associated with gastrointestinal disorders, such as perforation, obstruction, or pancreatitis.
  - you are currently suffering from convulsions, a muscle disorder or severe muscle weakness (myasthenia gravis).
  - long-term treatment with this medicine is required, especially in the case of long-term treatment in the elderly who are at greater risk of side effects.
  - a shot (vaccination) is absolutely necessary: the administration of vaccines containing live or live-attenuated viruses is not recommended. Depending on the type of vaccine, the vaccination can either be dangerous and cause an infection, or it may be ineffective and not protect you from the disease. Always tell the person who is going to vaccinate you that you are or have been treated with [Name].

- Before treatment, tell your doctor if you have a tumour of the adrenal gland (known as pheochromocytoma).
- Tell your doctor if you suffer from scleroderma (also known as systemic sclerosis, an autoimmune connective tissue disease) because an increased risk of scleroderma renal crisis has been observed with the use of corticosteroids.
- Consult your doctor if you suffer from Cushing's syndrome, a condition in which too little thyroid hormones are produced (hypothyroidism) or if you are in a situation of exceptional stress or will soon be exposed to a situation of exceptional stress.
- Tell your doctor that you are using this medicine before having laboratory tests.
- Tell your doctor if you have been allergic to any medicine in the past.
- Tell your doctor if you have thromboembolic disorders (blood clots blocking the arteries).
- Tell your doctor if you have high blood pressure.
- Tell your doctor if you have Kaposi’ s sarcoma (a type of cancer that starts on the skin).
- Your doctor may recommend a low sodium diet and give you extra potassium if you are treated with high doses.
- The lowest possible dose to control the disease should be used and when dose reduction is possible it should be gradual.
- If you are taking any other medicines, please also read "Other medicines and [Name]".

Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents
The growth and development of new-borns and children under long-term treatment should be monitored regularly by a doctor, as growth retardation may occur with long-term treatment. If necessary, treatment should be administered every other day.

Infants and children on long-term treatment are particularly at an increased risk of intracranial hypertension.

High doses of this medicine can cause pancreatitis in children.

Other medicines and Methylprednisolon Eurogenerics
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- Some medicines may increase the effects of Methylprednisolon Eurogenerics and your doctor may wish to monitor you carefully if you are taking these medicines, including medicines used to treat HIV infections (cobicistat and protease inhibitors such as indinavir and ritonavir).
- The combination of glucocorticoids with certain other anti-inflammatory drugs increases the risk of certain gastrointestinal disorders.

- Glucocorticoids may increase the need for insulin or oral blood sugar-lowering agents in diabetics. The combination of glucocorticoids with thiazide diuretics increases the risk of hyperglycaemia (elevated blood sugar) and a lack of potassium in the blood.
- There is also an increased risk of a shortage of potassium in the blood when corticosteroids are combined with the following medicines: amphotericin B (medicine used for certain fungal infections), xanthene or beta-2 mimetics (medicines used for asthma).
- Glucocorticoids suppress the ability to fight infections. Certain vaccinations are therefore not recommended.
- Glucocorticoids can affect the effect of anticoagulants (medicines that inhibit blood clotting).
- The effect of glucocorticoids can be inhibited or enhanced when they are coadministered with medicines such as:
  - ketoconazole, itraconazole;
  - certain macrolide antibiotics such as erythromycin, clarithromycin, troleandomycin;
  - barbiturates, phenobarbital, phenylbutazone, phenytoin, carbamazepine;
  - muscle relaxants (medicines used in anaesthesia such as vecuronium, pancuronium);
  - cholinesterase inhibitors;
  - rifampicin, isoniazid, which are used for tuberculosis;
  - some medicines for nausea and vomiting (aprepitant, fosaprepitant);
  - diltiazem;
  - aminoglutethimide;
  - some oral contraceptives (ethinylestradiol/norethindrone);
  - some immunosuppressants (cyclophosphamide, tacrolimus).
- On the other hand, the action of acetylsalicylic acid and other salicylates can be reduced when administered with glucocorticoids.
- The administration of glucocorticoids together with non-steroidal anti-inflammatory drugs may increase the risk of gastrointestinal ulcers and bleeding.
- Acetylsalicylic acid and nonsteroidal anti-inflammatory drugs should be used with caution in combination with glucocorticoids.
- Convulsions may occur when glucocorticoids are administered concomitantly with ciclosporin.

Methylprednisolon Eurogenerics with food and drink
Grapefruit juice may affect the effect of Methylprednisolone Eurogenerics.

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

Pregnancy
Use of Methylprednisolon Eurogenerics during pregnancy is generally not advised, unless in consultation with your doctor. If you become pregnant while using this medicine, you must see your doctor.
If long-term treatment needs to be discontinued during pregnancy, this must be done gradually.

New-borns whose mothers have been treated with large amounts of corticosteroids during pregnancy should be closely monitored for low birth weight and symptoms of adrenal insufficiency.

Breast-feeding
Corticosteroids pass into breast milk. Therefore, the use of methylprednisolone during the breast-feeding period is not recommended, unless this happens in consultation with your doctor.

Driving and using machines
Side effects such as a feeling of dizziness, dizziness, visual disorders and fatigue are possible after treatment with corticosteroids. You may not drive or use machines if you experience any of these disorders.

Methylprednisolon Eurogenerics contains lactose monohydrate and sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Methylprednisolon Eurogenerics contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Methylprednisolon Eurogenerics

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

The recommended dose and duration of treatment depend on the condition. Your doctor will determine how much of this medicine you should use and for how long.

Methylprednisolon Eurogenerics should be taken with a sufficient amount of water or milk.
The tablets can be divided into equal doses.

If you take more Methylprednisolon Eurogenerics than you should
If you take more Methylprednisolon Eurogenerics than you should, contact your doctor or pharmacist immediately.
Acute overdose with this medicine does not result in immediately visible side effects. However, chronic overdose does lead to typical symptoms such as moon face, swelling and fluid retention. There is no specific antidote in case of overdose: treatment consists of the administration of supportive care and treatment to relieve symptoms.
Methylprednisolone is dialysable.

If you forget to take Methylprednisolon Eurogenerics
Contact your doctor. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Methylprednisolon Eurogenerics
Your doctor will tell you how long to use this medicine. Medical supervision is recommended when stopping long-term treatment and the treatment should be stopped gradually. Your doctor must watch for symptoms of insufficient adrenal function including weakness, drop in blood pressure when standing up from a lying position, depressed mood.

If treatment is stopped suddenly, a 'withdrawal syndrome' can occur with the following symptoms: significant loss of appetite, nausea, vomiting, lethargy, headache, fever, joint pain, damage to the superficial layers of the skin, muscle pain, weight loss and/or low blood pressure.

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.

If you belong to the following special risk groups, you will need regular medical attention:
- Children: growth retardation is possible with long-term treatment
- Diabetes: there may be an increased need for insulin or other blood sugar-lowering medicines
- Patients with increased blood pressure
- Patients with mood disorders
- Patients with bone decalcification
- Patients with kidney function disorders
- Patients with herpes simplex or zona of the eye, due to the risk of perforation of the cornea

The risk of side effects is generally small if this medicine is only used for a short period.
It can increase if high doses are used for a long period.

Common side effects (may affect up to 1 in 10 people):
- Muscle weakness
- Growth disorders in children
- Stomach ulcer (with risk of perforation and blood loss)
- Delayed wound healing
- Thin and fragile skin
- Acne
- Sodium retention
- Fluid retention
- Euphoria
- Depression
- Moon face (Cushing's syndrome)
- Withdrawal syndrome (see section 3 ‘If you stop taking Methylprednisolone EG’)
- Cataract
- Infection
- Increased blood pressure (hypertension)
- Decrease of blood potassium levels

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

Frequency not known (cannot be determined based on available data)
- Muscle disease (myopathy)
- Bone decalcification (osteoporosis)
- Fractures
- Spinal compression fractures due to sagging spine
- Torn tendons (especially the Achilles tendon)
- Destruction of tissue
- Joint diseases
- Reduction of muscle mass
- Pain in the muscles and joints
- Stomach bleeding
- Intestinal perforation
- Inflammation (e.g. of the pancreas or oesophagus)
- Swollen stomach
- Stomach pain
- Diarrhoea
- Nausea
- Vomiting
- Disturbed digestion
- Changes in blood values in liver function tests
- Increase of liver enzymes
- Inflammation of the liver (hepatitis)
- Ecchymosis
- Small spots of bruising under the skin
- Skin changes
- Skin redness
- Angioedema (allergic reaction)
- Itching (pruritus)
- Urticaria
- Skin rash
- Excess hair growth in women (hirsutism)
- Excess sweating
- Streaks on the skin
- Acidification of the blood (metabolic acidosis)
- Abnormal blood fat levels (dyslipidaemia)

- Decreased tolerance for sugar
- Hypokalaemic (low blood potassium) alkalosis (increased blood alkalinity)
- Increased need for insulin or medicines that reduce blood sugar in diabetes
- Signs of latent diabetes
- Negative nitrogen balance
- Increased appetite (with possible weight gain)
- Accumulation of fat tissue on localized parts of the body
- Dizziness
- Increased pressure in the brain (especially benign intracranial hypertension)
- Headache
- Convulsions (seizures/fits)
- Amnesia
- Cognitive disorder
- Psychotic disorders (including mania, delirium, hallucinations, and schizophrenia)
- Psychotic behaviour
- Mood disorders (including emotional lability, drug dependence, suicidal thoughts)
- Mental disorder
- Personality disorders
- Mood changes
- Confusion
- Abnormal behaviour
- Anxiety
- Insomnia
- Irritability
- Hypopituitarism
- Irregular menstruation
- Glaucoma
- Bulging of the eye
- Disease of the retina and choroid membrane
- Opportunistic infection
- Inflammation of the peritoneum (peritonitis)
- Allergic reactions and serious, potentially fatal hypersensitivity reactions (including increased sensitivity to a foreign substance)
- Acceleration heartbeat
- Ruptured myocardium (heart muscle) following a heart attack
- Congestive heart failure (in susceptible patients)
- Blood clots (thrombosis)
- Decreased blood pressure (hypotension)
- Increased clotting of the blood
- Increase of white blood cells
- Pulmonary embolism (obstruction of a blood vessel near the lungs)
- Hiccups
- Fatigue
- Feeling unwell (malaise)
- Peripheral oedema
- Increased pressure inside the eye (intraocular pressure)
- Decrease in ability to tolerate carbohydrates
- Increased excretion of calcium
- Increased blood urea
- Suppression of reactions to skin allergy tests
- Slow heart rate

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. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Methylprednisolon Eurogenerics

Keep this medicine out of the sight and reach of children.
Blister packs: This medicinal product does not require any special storage conditions.
Bottles: Do not store above 30°C.
After first opening (bottles): Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the blister/label and carton 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 Methylprednisolon Eurogenerics contains
The active substance is methylprednisolone.
The other ingredients are lactose monohydrate, sucrose, sodium starch glycolate (Type A), anhydrous colloidal silica (E551), magnesium stearate (E572).

What Methylprednisolon Eurogenerics looks like and contents of the pack
Methylprednisolon Eurogenerics 4 mg tablets: White to off white, round, biconvex tablets, plain on both sides.
Methylprednisolon Eurogenerics 16 mg tablets: White to off white, oval, biconvex tablets, breakline on one side and embossed '16' on the other side.

Methylprednisolon Eurogenerics 4 mg tablets are available in in blister packs containing 20, 30 or 100 tablets and bottles containing 20, 30 or 100 tablets.
Methylprednisolon Eurogenerics 16 mg tablets are available in blister packs containing 20, 30, 50 or 100 tablets and bottles containing 20, 50 or 100 tablets .

Not all pack sizes may be marketed.

Marketing Authorisation Holder
EG (Eurogenerics) NV - Heizel Esplanade b22 - 1020 Brussel - België

Manufacturer
Sanico NV - Veedijk 59 - B- 2300 Turnhout - Belgiê
EG (Eurogenerics) NV - Heizel Esplanade B 22 - B-1020 Brussel - België

This medicinal product is authorised in the Member States of the EEA under the following names:
NL: Methylprednisolon Eurogenerics 4 mg – 16 mg tabletten
BE: Methylprednisolone EG 4 mg – 16 mg tabletten
LU: Methylprednisolone EG 4 mg – 16 mg comprimés

In het register ingeschreven onder:
Methylprednisolon Eurogenerics 4 mg tabletten: RVG 116593
Methylprednisolon Eurogenerics 16 mg tabletten: RVG 116594

Deze bijsluiter is voor het laatst goedgekeurd in april 2021.