PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Methylprednisolone 40 mg, 500 mg and 1000 mg
Powder for solution for injection

methylprednisolone (as sodium succinate)

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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 nurse. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. WHAT METHYLPREDNISOLONE IS AND WHAT IT IS USED FOR

Methylprednisolone contains Methylprednisolone Sodium Succinate.
Methylprednisolone belongs to a group of medicines called corticosteroids or steroids.

Corticosteroids are produced naturally in your body and are important for many body functions.
This medicine will be administered to you by a doctor or nurse to help treating your symptoms caused by the following conditions:

Corticosteroids are indicated in many diseases, namely:
- Endocrine diseases
- Rheumatological and collagen diseases
- Dermatological diseases
- Allergic conditions
- Ophthalmological diseases
- Gastrointestinal diseases
- Respiratory diseases
- Haematological diseases
- Neoplastic diseases
- Oedematous conditions
- Nervous system diseases
- Cardiovascular disturbances
- Haemorrhagic, traumatic and surgical shock

Your doctor may use this medicine to treat other conditions besides the ones mentioned above.
If you have any doubts about why this medicine was prescribed to you, talk to your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE METHYLPREDNISOLONE

Do not use Methylprednisolone:
- If you think you may have suffered an allergic reaction, or any other kind of reaction after the administration of Methylprednisolone or of any other medicine containing corticosteroids. An allergic reaction can cause a skin rash or redness, swollen face or lips, or shortness of breath.
- if you are allergic to methylprednisolone sodium succinate or any of the other ingredients of this medicine (listed in section 6).
- if you have had a systemic fungal infection diagnosed.
- by intrathecal administration.
- by the epidural route of administration.

While you are being treated with this medicine as an immunosuppressant, you cannot be vaccinated with live or attenuated vaccines.

If you have any of the above mentioned, inform your doctor immediately.

Warning and precautions
Talk to your doctor or pharmacist before taking this medicine if you have any of the following conditions. Your doctor may have to monitor your treatment more closely, change the dosage or give you another medicine.

- chicken pox, measles, herpes ocular infection, or any other infection. If you think you may have been in contact with someone with chicken pox or measles and you have not yet had any of those diseases, or if you are not sure you had them;
- If you have an over-active thyroid gland (hyperthyroidism)
- Fungal, viral, bacterial or parasite infections
- Psychiatric disorders (including euphoria, insomnia, mood disorders, personality disorders, major depression, psychotic manifestations or suicidal ideations). This includes having had previous disorders when you took steroid like Methylprednisolone
- Diabetes
- Seizures
- Glaucoma (increased eye blood pressure), or other problems in the eyes
- Heart problems, including congestive heart failure
- Hypertension (high blood pressure) or changes in blood fat (dyslipidaemia)
- Hypothyroidism (thyroid with decreased activity)
- Kidney diseases
- Kaposi's sarcoma (a type of skin cancer)
- Serious muscular problems (e.g.: myasthenia graves, a disease that causes tired and weak muscles)
- Osteoporosis (brittle bones)
- Stomach ulcers or other serious stomach, pancreas or intestine issues
- Tuberculosis, or if you have suffered tuberculosis in the past
- Cushing's syndrome
- Pheochromocytoma (suprarenal glands' cells tumour)
- Tendency to form blood clots
- Liver disease
- Scleroderma (also known as systemic sclerosis, an autoimmune disorder)

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

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using methylprednisolone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with methylprednisolone. You may need additional treatment to alleviate this condition.
If methylprednisolone is given to premature babies, it may be necessary to monitor the cardiac function and structure.

When corticosteroids are administered during cancer treatments, tumour lysis syndrome can occur. Inform your doctor if you have cancer and tumour lysis syndrome symptoms, such as cramps, muscle weakness, feeling confused, irregular heartbeat, loss or changes of vision and difficulty breathing.

Children
Babies and children in prolonged treatment with corticosteroids should have their growth and development closely monitored. Growth suppression can occur in children receiving daily prolonged treatment, with divided doses of glucocorticoids. The use of this dosage regimen should be solely used in the more serious cases.

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

Tell your doctor if you are taking any of the following, as they may affect the mode of action of Methylprednisolone or of another medicine:
- Anticoagulants – used to thin the blood
- Neuromuscular blocking agents, such as pancuronium and vecuronium
- Anticholinesterases – used to treat myasthenia gravis (a muscular disease)
- Antibiotics – such as isoniazid, erythromycin, clarithromycin, troleandomycin or rifampicin
- Antifungals used to treat fungal infections, such as ketoconazole or itraconazole
- Antivirals – such as indinavir and ritonavir
- Acetylsalicylic acid and non-steroid anti-inflammatory drugs (NSAIDs), such as ibuprofen, used to treat light and moderate pain
- Anticonvulsants used to treat epilepsy, such as carbamazepine, phenobarbital and phenytoin
- Immunosuppressants – including cyclosporin, cyclophosphamide and tacrolimus
- Antidiabetics
- Aprepitant and fosaprepitant – medicines used for nausea and vomiting
- Diltiazem – used for heart problems or high blood pressure
- Oral contraceptives – used to prevent pregnancy
- Aminogluthimide
- Diuretics (potassium depletion agents)

Some medicines may increase the effects of Methylprednisolone and your doctor may want to monitor you carefully if you are taking these medicines, including medicines such as antivirals (ritonavir, indinavir) and pharmacokinetic enhancers (cobicistat), used to treat HIV.

Vaccines – inform your doctor or nurse if you have been recently vaccinated or are about to be vaccinated. You should not be vaccinated with live or attenuated vaccines while using this immunosuppressant medicine. Other vaccines could be less effective.
Patients undergoing corticosteroid treatment should not be vaccinated against smallpox.

If you are taking long-acting treatments for diabetes, high blood pressure or liquid retention, inform your doctor, as it could be necessary to adjust the dosage of those medicines.

Before you have any operation, tell your doctor, dentist or anaesthetist that you are taking this medicine

If you require a test or blood analysis to be carried out by your doctor or at an hospital, its important that you tell your doctor or nurse that you are taking Methylprednisolone. This medicine can affect the results of some tests.

Methylprednisolone with food and drinks
Do not drink grapefruit juice during the treatment with Methylprednisolone.

Pregnancy, breast-feeding and fertility

Pregnancy
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.
Methylprednisolone is not recommended during pregnancy or breastfeeding, except in cases of absolute need.

Breast-feeding
Corticosteroid pass to breastmilk and should only be given to women who breastfeed if the potential benefits of the treatment are greater than the risks for the baby.

In animal studies, corticosteroids were demonstrated to reduce fertility.

Driving and using machines
Some side effects may occur, such as dizziness, vertigo, visual alterations and tiredness after treatment with corticosteroids. If you have these symptoms, you should not drive or use machines.

Methylprednisolone contains sodium

Each vial of Methylprednisolone 40 mg contains less than 1 mmol sodium (23 mg) per 40 mg, that is to say essentially "sodium-free".

Each vial of Methylprednisolone 500 mg contains 53.18 mg sodium per 500 mg. This is equivalent to 2.66% of the recommended maximum daily dietary intake of sodium for an adult.

Each vial of Methylprednisolone 1000 mg contains 167.59 mg sodium per 1000 mg. This is equivalent to 8.38% of the recommended maximum daily dietary intake of sodium for an adult.
If you are on controlled sodium (salt) diet tell your doctor in case your sodium intake needs to be adjusted.

3. HOW TO USE METHYLPREDNISOLONE

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Methylprednisolone will be administered to you by a doctor or nurse.

Method of Administration
Methylprednisolone can be administered by intravenous or intramuscular injection or by intravenous perfusion. The preferential method for initial emergency treatment is the intravenous injection.

Posology
Your doctor will decide the place of injection, how much of the medicine and how many injections you will receive depending on the condition you are being treated for and its severity.
Your doctor or nurse will administer to you the lowest dose for the shortest possible period of time possible to get effective relief of your symptoms.
Your doctor will decide when you should switch to an oral treatment.

If you use more Methylprednisolone than you should
In case of overdose, there is no specific antidote available; the treatment is supportive and symptomatic.

If you took more than Methylprednisolone you should
Since this treatment is administered with close medical supervision, it is unlikely that you were not administered a dose. However, you should inform your doctor if you think a dose was not administered to you.

Methylprednisolone 40 mg, 500 mg and 1000 mg
Powder for solution for injection

The following information is intended for healthcare professionals only:

Method of administration:
Methylprednisolone may be administered intravenously or intramuscularly, the preferred method for emergency use being intravenous injection given over a suitable time interval.

a) Preparation of solution for injection (reconstitution):

Methylprednisolone solution for injection should be prepared by dissolving the powder in an appropriate volume of water for injection, as shown in the table below.

Methylprednisolone presentation:	Solvent quantity (WFI):	Final solution concentration:
40 mg	1.2 ml	40 mg/ml
125 mg	2.1 ml	62.5 mg/ml
250 mg	4 ml	62.5 mg/ml
500 mg	8 ml	62.5 mg/ml
1000 mg	16 ml	62.5 mg/ml

If you stop taking Methylprednisolone
Do not stop treatment nor reduce your dose without your doctor's advice. Your doctor will decide when you should stop your treatment and advise you on how to stop Methylprednisolone gradually.
You must stop Methylprednisolone slowly to avoid withdrawal symptoms. These symptoms can include loss of appetite, nausea, vomiting, apathy, headache, fever, muscle and joint pain, skin peeling, weight loss and 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.

Contact your doctor immediately if you get any of the following symptoms:
- 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.
- Acute pancreatitis, stomach pain that irradiates towards the back, possibly accompanied by vomit and loss of consciousness.
- Ulcers with bleeding or perforation, symptoms of which are stomach pain (mainly if it seems to spread to your back), black or bloody stools and/or vomiting blood.
- Infections. This medicine can hide or change some signs and symptoms of some infections, or reduce your resistance to infections, making it more difficult to diagnose at an early state. Symptoms may include increased temperature and feeling unwell. Symptoms of reoccurring tuberculosis may include coughing blood or chest pain. Methylprednisolone may also make you more likely to develop a severe infection.
- Increased skull pressure in kids, whose symptoms are headaches with vomiting, lack of energy and drowsiness. Usually, this side effect usually occurs after treatment is stopped.

It is important to CONTACT YOUR DOCTOR IMMEADITELY if you get any of the above-mentioned symptoms.

Do not stop taking Methylprednisolone, however inform your doctor immediately if you feel any of the following side effects, or detect another side effect not mentioned in this leaflet.

Regarding the frequency of the side effects, it can be:
- very common (may affect more than 1 in 10 patients)
- common (may affect between 1 and 10 patients in 100)
- uncommon (may affect between 1 and 10 patients in 1000)
- rare (may affect up to 1 in 1000 patients)
- not known (frequency cannot be estimated from the available data)

Infections and infestations
Common: Infection (including increased susceptibility and severity of infections with suppression of clinical symptoms and signs).
Not known: Opportunistic infection, peritonitis (inflammation of the abdominal cavity coating)

Blood and lymphatic system disorders
Not known: Increase of white blood cells (leucocytes)

Immune system disorders
Not known: Allergy to medicines, anaphylactic and anaphylactoid reaction (serious anaphylactic reaction)

Endocrine disorders
Common: Cushingoid
Not known: Decreased hypophysis gland function, steroidal abstinence syndrome

Metabolism and nutrition disorders
Common: sodium retention, water retention
Not known: excess acidity in the blood, decreased tolerance to glucose, hypokalaemic alkalosis, dyslipidaemia, (change in the levels of certain fats in the blood), increase in the need for insulin (or hypoglycaemic oral agents in diabetics), increased appetite (which can lead to weight gain), accumulation of fat tissue on localized parts of the body.

Psychiatric disorders
Common: a wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, drug dependence and suicidal thoughts). The following events where more common in children: mood swings, strange behaviour, difficulty sleeping, irritability
Not known: affective disorders (including affective instability, medicine dependency, suicidal thoughts), psychotic disorders (including mania, delirium, hallucinations and schizophrenia [worsening]), confused state, mental disorders, anxiety, personality disorders, mood swings, abnormal behaviour, difficulty sleeping, irritability (in adults)

Nervous system disorders
Not known: increased intracranial pressure (with optical papilla oedema [benign intracranial hypertension]), seizure, memory loss, difficulty thinking, dizziness, headache

Eye disorders
Common: cataracts (opacity in the lens of the eye)
Not known: exophthalmos (protrusion of the eye outside the orbit), glaucoma (increased eye globe pressure), disease of the retina and choroid membrane, blurred vision

Ear and labyrinth disorders
Not known: vertigo

Cardiac disorders
Not known: congestive heart failure (in susceptible patients), changes in heartbeat

Vascular disorders
Common: high blood pressure
Not known: blockage of a blood vessel by clots, low blood pressure, Increased clotting of the blood

Respiratory, thoracic and mediastinal disorders
Not known: blockage of pulmonary artery or one of its branches by clots, hiccups

Gastrointestinal disorders
Common: peptic ulcer (with possible perforation and bleeding of the peptic ulcer)
Not known: bleeding in the stomach, intestinal perforation, pancreas inflammation, ulcerative esophagitis, esophagitis (inflammation of the mucosa that covers the inside of the oesophagus), abdominal pain, abdominal distension, diarrhoea, dyspepsia (pain or malaise in the upper abdomen), nausea

Hepatobiliary disorders
Not known: Methylprednisolone can damage your liver, hepatitis and increase of liver enzymes have been reported.

Skin and subcutaneous tissue disorders
Common: bruise (small purple lesions), skin atrophy (thin fragile skin), acne
Not known: angioedema (skin swelling), petechiae (small purple/red spots on the skin), stretch marks on the skin, change in skin colour, hirsutism (increase in hair), skin rash, erythema, itching, urticaria, increased sweating

Musculoskeletal and connective tissue disorders
Common: decrease in the normal growth of children and adolescents, osteoporosis (decrease in bone mass), muscle weakness
Not known: osteonecrosis (bone degradation), bone fracture, decrease in muscle, joint pain and problems, muscle pain and problems

Reproductive system and breast disorders
Not known: irregular periods

General disorders and administration site conditions
Common: peripheric oedema, difficulty in wound healing
Not known: injection site reaction, tiredness, general malaise

Investigations
Frequent: decreased blood potassium
Not known: Increased liver enzymes in the blood (alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase in the blood), increased eye pressure, decreased tolerance to carbohydrates; increased urine calcium, suppression of skin test reactions, increased blood urea

Injury, poisoning and procedural complications
Not known: rupture tendon (particularly Achilles tendon), vertebral column compression fracture

It is important that you inform your doctor or nurse that you are undergoing treatment with Methylprednisolone if you need to do a blood test.

Reporting undesirable effects
If you have any side effects, including possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also communicate undesirable effects directly through:

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE METHYLPREDNISOLONE

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

Store below 25°C.
Keep the vial in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the vial's label and carton after EXP. The expiry date refers to the last day of that month.

Instructions to insert the needle on the rubber stopper:

To reduce the probability of rubber stopper fragmentation, and in accordance with European Pharmacopeia, it is recommended the use of a needle with an external diameter of 0.8mm (equivalent to a 21G) for the reconstitution of the product.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Methylprednisolone contains

- The active substance is methylprednisolone (as sodium succinate).
- The other ingredients are sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous and sodium hydroxide. The 40 mg vial also contains glucose.

What Methylprednisolone looks like and contents of the pack

Methylprednisolone is a white or nearly white powder, packed in a clear glass vial closed with a rubber stopper and a flip-off aluminium capsule.

Each vial of Methylprednisolone 40 mg contains 53.0 mg of methylprednisolone sodium succinate, equivalent to 40 mg of methylprednisolone.
Each vial of Methylprednisolone 500 mg contains 663.0 mg of methylprednisolone sodium succinate, equivalent to 500 mg of methylprednisolone.
Each vial of Methylprednisolone 1000 mg contains 1,326.0 mg of methylprednisolone sodium succinate, equivalent to 1000 mg of methylprednisolone.

Marketing Authorisation Holder

Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó 8, 8A e 8B – Fervença
2705-906 Terrugem SNT
Portugal

Distributed by:
Consilient Health (UK) Ltd.
No.1 Church Road,
Richmond upon Thames,
Surrey. TW9 2QE.

Manufacturer

Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó 8, 8A e 8B – Fervença
2705-906 Terrugem SNT
Portugal

Manufacturer (for 40 mg strength only)

Hikma Italia S.p.A.
Viale Certosa, 10
27100 Pavia
Italy

This leaflet was last revised in 12/2024.

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b) Preparation of infusion solution

For intravenous infusion the initially prepared solution may be diluted with 5% dextrose in water for injection, 0.9% Sodium Chloride in water for injection (isotonic saline solution), or 5% dextrose in isotonic saline solution. To avoid compatibility problems with other drugs Methylprednisolone should be administered separately, only in the solutions mentioned.

Parenteral drugs products should be inspected visually for particulate matter and discoloration prior to administration.

After reconstitution as recommended, use immediately, discard any remainder. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2º to 8ºC, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instructions to insert the needle on the rubber stopper:
To reduce the probability of rubber stopper fragmentation, and in accordance with European Pharmacopeia, it is recommended the use of a needle with an external diameter of 0.8mm (equivalent to a 21G) for the reconstitution of the product.