Package leaflet: Information for the patient

Methylprednisolone-Tchaikapharma 40 mg powder and solvent for solution for injection
(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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, contact your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Methylprednisolone-Tchaikapharma is and what it is used for

Methylprednisolone-Tchaikapharma belongs to a group of medicines called corticosteroids or steroids.

Methylprednisolone-Tchaikapharma is used to treat:

- Hormonal diseases: for example, if the adrenal glands does not work properly for any reason, so the body does not produce enough of its own hormones; in a certain type of blood circulation insufficiency (shock in adrenal insufficiency or shock, not susceptible to standard treatment where there may be only deficiency in the adrenal cortex); in patients who are about to undergo surgery, have severe trauma or any other disease, coupled with impaired adrenal function; hypercalcaemia (elevated blood calcium levels) in cancer patients; a certain type of thyroid inflammation (nonpurulent thyroiditis); in congenital overgrowth of the adrenal glands.
- Rheumatic diseases: rheumatoid arthritis (autoimmune inflammatory disease affecting the joints and/or other parts of the body in adults or children); acute and subacute bursitis (inflammation of the bursa), acute nonspecific tenosynovitis (inflammation of the vagina muscle tendon), acute gouty arthritis (inflammation of the joint in gout), posttraumatic osteoarthritis (inflammation of the joint after trauma), synovitis in osteoarthritis (inflammation of the intra-articular mucosa), epocondylitis (inflammation of the end of some bones or the tendons attached to them). It is also used as an additional therapy for ankylosing spondylitis (joints of the spine and pelvis ossify and adhere), psoriatic arthritis (joint inflammation of psoriasis).
- Collagenosis (connective tissue diseases): inflammation of the muscles (such as dermatomyositis or polymyositis); systemic lupus erythematosus (autoimmune disease characterized by rash accompanied by fever, arthritis, inflammation of the blood vessels, kidney disorders and disorders affecting the brain); acute rheumatic myocarditis (affecting the heart muscle in rheumatism); other diseases of the connective tissue (such as polyarteritis nodosa or Goodpasser's syndrome).
- Skin diseases: pemphigus vulgaris (blistering of the skin), other skin disorders: Stevens-Johnson syndrome (severe disease accompanied by blistering of the skin, mouth, eyes and half organs);

exfoliative dermatitis; severe psoriasis; severe seborrheic dermatitis; bullous herpetiform dermatitis (a disease characterized by symmetrically located rashes and severe itching), fungal infections.

- Allergic conditions: bronchial asthma, severe forms of hay fever and other allergies accompanied by runny nose; allergies to certain drugs (such as penicillin) and serum sickness (allergy to vaccines produced from animal serum); dermal allergy due to contact with certain substances (contact dermatitis), laryngeal edema and others.
- Eye diseases: iritis or erythrocyclit (inflammation of the front of the eye); posterior uveitis (inflammation of the back of the eye); optic neuritis (inflammation of the optic nerve), inflammation of the anterior ocular segment, allergic conjunctivitis or other allergic changes (corneal edema) and other eye diseases (ophthalmic shingles, chorioretinitis, keratitis).
- Intestinal diseases: inflammation and ulcers of the colon (ulcerative colitis); inflammation of different parts of the intestine (regional enteritis).
- Pulmonary inflammation: pulmonary sarcoidosis (inflammation of the tissues and lymphatic glands of the lungs); tuberculosis that progresses rapidly or has spread to other parts of the lung (concomitantly with anti-tuberculosis agents); inflammation caused by the entry of stomach contents or vomiting in the lungs in unconsciousness (aspiration pneumonitis); moderate to severe pneumonia caused by pneumocystis carinii, in AIDS patients (as adjunctive therapy) and other lung diseases (Berylliosis, Leafller Syndrome and Chronic Obstructive Pulmonary Disease).
- Blood disorders: idiopathic thrombocytopenic purpura in adults (increased tendency to subcutaneous haemorrhage and bleeding due to low blood counts involved in blood clotting); Autoimmune haemolytic anemia (when the immune system attacks your own red blood cells (erythrocytes) and other anemias.
- Malignancies: leukemia (excessive white blood cell formation in the bone marrow); lymphatic system cancer that usually affects lymph nodes (glands) and spleen; for improving the quality of life in patients with end-stage cancer.
- Fluid retention: to increase diuresis (urinary excretion) in nephrotic syndrome (kidney disease).
- Other conditions: multiple sclerosis; tuberculosis infection causing inflammation of the meninges (cerebral lining), together with anti-tuberculosis agents; brain edema induced by a tumor; early treatment of spinal cord injury; organ transplantation; prophylaxis of nausea and vomiting in the treatment of cancer.

Your doctor may use Methylprednisolone-Tchaikapharma for treatment of conditions other than those listed above. Ask your doctor if you are not sure why he/she has prescribed it to you.

2. What you need to know before you take Methylprednisolone-Tchaikapharma

Do not use Methylprednisolone-Tchaikapharma

- If you are allergic to the active substance or to any of the other ingredients of this medicine (listed in section 6).
- If you have systemic fungal infection.
- In premature or newborn babies.
- If the use of live vaccines is required.
- Via an intrathecal or epidural route of administration.

Warnings and precautions

Talk to your doctor or pharmacist before taking Methylprednisolone-Tchaikapharma

- If you are pregnant and this medicine is prescribed to you, your baby will need extra checks soon after birth to make sure its adrenal glands work normally.
- If you are breast-feeding during treatment, your baby will need extra checks to make sure it is not being affected by the medicinal product.

- If you have any infections local or general (including measles and chickenpox) or abscesses.
- If you are going to have a vaccination.
  Have you recently been vaccinated? (Tell your doctor or nurse that you are taking Methylprednisolone-Tchaikapharma if you are going to be vaccinated. No live vaccines should be used during treatment with this medicine and other vaccines may be less effective).
- If you have tuberculosis.
  Have you ever had tuberculosis in the past? Have you had a positive tuberculosis test?
- If you have had a severe mental illness in the past (for example, emotional instability, depression, hallucinations).
- If you have previously been treated with steroids, had it caused psychosis (a mental illness for which ambulatory or hospital treatment should have taken place)?
- If you have a disease with convulsions.
- If you have a myasthenia gravis (when you feel weak in some or all of the muscles, or get tired easily).
- If you have ever had an eye infection caused by a herpes simplex virus.
  Do you have a occular herpes infection (an ulcer of the eye that had appeared long ago or a sore eye)?
- If you have heart failure.
  Do you have swelling around your ankles, difficulty breathing and palpitations?
- If you have or are prone to a thromboembolic disorder (a blood clot that is circulating in your blood vessels) or you have high blood pressure.
- If you have problems with the digestive tract such as stomach or intestinal ulcer (can cause stomach pain), diverticulitis (inflamed "pockets" on the inner wall most often in the large intestine causing left-sided abdominal pain, constipation or diarrhea) or ulcerative colitis (swelling and ulcers in the intestines).
  Although steroids are very effective in treating inflammation in ulcerative colitis, they can increase the risk of bleeding or rupture of the intestinal tract. Have you recently had stomach, appendix, gallbladder, pancreas or small intestine or large intestine surgery?
- If you have ever had myopathy (muscle problems with weakness or pain, especially of the lower limbs and headache) when treated with steroids.
- If you have osteoporosis (brittle bones).
- If you have kidney problems (leading to increased or decreased urine output).
- If you have hypoprothrombinemia (a condition associated with reduced blood capacity to clot).
- If you have brain trauma.
  There are indications that this drug should not be routinely used to treat brain injuries.
- If you have a phaeochromocytoma (see adrenal tumor).

The appearance of acute hepatitis (inflammation of your liver) when this drug is given to you via an intravenous infusion is not ruled out. This undesirable event may occur several weeks after starting treatment and is expected to resolve after termination.

If you have any tests taken, tell the doctor that you are taking Methylprednisolone-Tchaikapharma.

Children and adolescents
The growth and development of infants and children undergoing continuous corticosteroid therapy should be closely monitored. There is a risk of inhibition of growth in children receiving long-term corticosteroid treatment in a daily dose divided into several intakes. The application of such a scheme should be limited to the most severe indications.

Infants and children undergoing continuous corticosteroid therapy are at particular risk of elevated intraocular pressure.
High doses of corticosteroids can cause pancreatitis (inflammation of the pancreas) in children.

Other medicines and Methylprednisolone-Tchaikapharma
Tell your doctor or pharmacist 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 medicines listed below:
- some antibiotics (e.g. trolandomicin, clarithromycin, erythromycin, isoniazid), antifungal medicines (e.g. itraconazole, ketoconazole), calcium antagonists (for the treatment of high blood pressure or angina such as diltiazem), certain antiviral medicines (including some medicines used to treat HIV such as indinavir, ritonavir, cubiclistat), antiemetics (medicines for the treatment of nausea and vomiting such as aprepitant, fosaprepitant) and birth control pills (e.g. ethinylestradiol/norethindrone) may reduce the release of methylprednisolone from your body, thus increasing the effect of Methylprednisolone-Tchaikapharma - if you are taking such medicines your doctor may need to adjust the Methylprednisolone-Tchaikapharma dosage and monitor you closely;
- some anticonvulsants (medicines to treat epileptic seizures, e.g. carbamazepine, phenobarbital, phenytoin) or antituberculosis medicines (e.g. rifampicin) may increase the release of methylprednisolone from your body, thus reducing the effect of Methylprednisolone-Tchaikapharma, therefore it is necessary to increase the dose of Methylprednisolone-Tchaikapharma to achieve the desired response;
- anticoagulants (coagulation inhibiting medicinal products): co-administration of Methylprednisolone-Tchaikapharma may both enhance and reduce their anti-clotting effect, so your doctor needs to closely monitor your coagulation parameters;
- neuromuscular blockers (medicines used to relax the muscles during anesthesia: simultaneous administration of Methylprednisolone-Tchaikapharma may affect their effect;
- anticholinesterase inhibitors (medicines used to treat diseases such as myasthenia gravis or glaucoma); Methylprednisolone-Tchaikapharma may weaken the effects of these drugs in myasthenia gravis;
- antidiabetic medicines (for the treatment of diabetes mellitus): Methylprednisolone-Tchaikapharma may increase your blood sugar and therefore change to your dose of antidiabetic medicines may be needed;
- aromatase inhibitors (for the treatment of breast cancer and ovarian cancer in postmenopausal women, e.g. aminoglutethimide) – Your doctor will pay special attention in case you have been on long-term treatment with Methylprednisolone-Tchaikapharma.
- acetylsalicylic acid and similar medicinal products called salicylates (usually used in pain and/or elevated body temperature caused by inflammation) – Methylprednisolone-Tchaikapharma enhances the release of aspirin and salicylates from the body – if you stop using Methylprednisolone-Tchaikapharma, their concentrations may suddenly increase and cause side effects such as ringing in the ears; If you have hypotrombiaemia (increased bleeding tendency), your doctor will be more cautious if you have to use Methylprednisolone-Tchaikapharma together with acetylsalicylic acid or salicylates;
- immunosuppressants (medicines to suppress the immune system in rheumatoid arthritis and psoriasis (e.g. cyclosporin), lymphoma, leukemia and breast cancer (e.g. cyclophosphamide), or in patients who have received an organ or bone marrow transplant (e.g. tacrolimus);
- blood potassium lowering products (e.g. diuretics): there is a risk of developing hypokalaemia (low blood potassium levels) when concomitantly used with Methylprednisolone-Tchaikapharma, so your doctor will monitor you closely for the development of this condition.

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

Children born to mothers who have received high doses of corticosteroids during pregnancy should be carefully monitored for signs of adrenal insufficiency (adrenal glands do not produce enough of their own corticosteroids).

Visual impairment (cataract) has been observed in infants born to mothers who have been treated for prolonged periods with corticosteroids during pregnancy.
Corticosteroids are excreted in breast milk.
There are data from studies in animals that show that steroids impair fertility (ability to conceive).
Due to the lack of sufficient evidence of human safety during pregnancy and lactation, this medicinal product should only be used in pregnant and breast-feeding mothers if absolutely necessary.

Driving and using machines
Although visual disturbances belong to rare undesirable effects, caution should be used when driving and operating machines.

Methylprednisolone-Tchaikapharma contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially sodium-free.

3. How to take Methylprednisolone-Tchaikapharma

Always use this medicine exactly as your doctor or pharmacist has told you. If you are not sure, ask your doctor or pharmacist.

Your doctor will decide what dose you should receive. The dose depends on your illness and its severity. Your doctor will always try to apply the lowest possible dose that provides a good result.

Your doctor may appoint a higher dose for several days to control your condition. If your condition is not controlled, he/she may change your treatment. Your doctor may make frequent examinations to make sure that you feel better.

The starting dose selected by your doctor will be continued until he/she determines that your condition has improved. If your doctor finds that your condition has improved, he/she will gradually reduce the dosage.

The medicinal product can be administered as an intravenous and intramuscular injection.

Use in children and adolescents
Methylprednisolone-Tchaikapharma may be prescribed in children. Usually a lower dose than in is prescribed, but this depends on the severity of the condition and the response to the treatment.

If you use more Methylprednisolone-Tchaikapharma than you should
Since this medicinal product is given as an injection under medical supervision, the possibility of omitting a dose or receiving a larger dose is unlikely. If you have any doubts, ask your doctor.

If you stop using Methylprednisolone-Tchaikapharma
Your doctor will decide when is the time to stop the treatment.

Treatment with Methylprednisolone-Tchaikapharma should not be discontinued abruptly, but with a gradual dose reduction, as your doctor will determine. This is because excessive dose reduction of the steroid can lead to acute adrenal insufficiency (adrenal glands do not produce enough of their own corticosteroids), very low blood pressure (causing dizziness and seizure) and a potentially fatal outcome. This is more likely to happen when repetitive doses have been received.

If your symptoms seem to return while the dose of Methylprednisolone-Tchaikapharma is being decreased, tell your doctor as soon as possible. If you get an infection, have an accident or you need surgery, a temporary dose increase may be necessary. If you have stopped taking the medicine shortly before infection, stroke or surgery, you may have to start taking it again for a short time.

When changing the dose, remind your doctor about any other medicines you are taking, especially medicines such as aspirin. Also, remember that you should tell any doctor who further examines you that you have been given Methylprednisolone-Tchaikapharma.

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.

There is a greater likelihood of getting side effects if you receive a large dose over a long period of time. Your doctor will give you the lowest possible dose to relieve your symptoms in the shortest possible time. This means that the risk of developing serious side effects is low, while the chance of improving your condition is great.

If you are over 65 years of age, side effects may be more serious. Your doctor will monitor your condition carefully.

Tell your doctor straight away if you notice any of the following or if you think you are at risk of infection (e.g. if you have been in contact with a person who has an infection).

Frequenct not known

- reduced resistance and increased risk of infection, abdominal skin infection (peritonitis);
- increase in white blood cell count (leukocytosis);
- allergy (hypersensitivity) to the medicine; acute severe allergic (anaphylactic) reaction with a sharp fall in blood pressure, urticaria, swelling and difficulty in breathing; severe allergic (anaphylactoid) reaction that causes difficulty breathing or dizziness.
- rounded or moon facies (Cushingoid facies), decreased pituitary activity (hypopituitarism), steroid withdrawal syndrome (abstention);
- increased levels of acidity of body fluids (metabolic acidosis), accumulation of fat in certain parts of the body (lipomatosis), retention of sodium, retention of liquids and salts in the body (alkalosis), increased blood fat (dyslipidemia), impaired glucose tolerance, increased need for insulin, increased appetite (which may lead to weight gain);
- mental disorder (including depression, euphoria, emotional instability, drug dependence, suicidal thoughts), obsessive-compulsive disorder (including mania, delusions, hallucinations and schizophrenia), mental disorder, personality changes, confusion, anxiety, sleeplessness, irritability;
- increased intracranial pressure, seizures, loss of memory (amnesia), cognitive impairment, dizziness, headache;
- retinal and choroidal diseases (chorioretinopathy), visual impairment (cataracts, glaucoma), ocular protrusion (exofatal);
- vertigo;
- congestive heart failure, abnormal heart rhythm (arrhythmia);
- increased blood clotting (thrombocytic events), increased or decreased blood pressure;
- obstruction of a blood vessel in the lungs from a blood clot formed in a leg or pelvic vein (pulmonary embolism), hiccups;
- peptic ulcer (esophagus), gastric perforation, gastric haemorrhage, pancreatic inflammation (pancreatitis), oesophageal ulcer (ulcerative oesophagitis), esophagitis, abdominal pain, diarrhea, indigestion, dyspepsia, nausea;
- methylprednisolone can harm your liver - hepatitis and hepatic enzymes increase have been reported;

- swelling around the eyes, mouth and in the oral cavity (aniogestrum); abnormal hair growth in women (hirsutism), purple spots (petechiae) or spot (ecchymosis) due to subcutaneous haemorrhage; cutaneous atrophy; redness of the skin (erythema); abundant sweating; Stretch marks on the skin; itching; rash; hives; acne; skin hypopigmentation;
- muscular weakness, muscular pain (myalgia), muscular disorder (myopathy), muscular arthropathy, brittle bones (osteoporosis), bone damage (osteonecrosis), fracture (pathological fracture), joint disease (arthropathy), joint pain (arthralgia), growth impairment;
- irregular menstruation;
- impaired wound healing, edema (peripheral), fatigue, malaise, reaction at the injection site;
- increased intraocular pressure, impaired body ability to break down carbohydrates (decreased carbohydrate tolerance), decreased potassium in the blood, increased calcium in the urine, increased alkaline phosphatase in the blood, increased blood urea, suppression of the reaction to skin tests;
- compression fracture (spinal fracture) of the spine, tendon rupture.

Important
Methylprednisolone-Tchaikapharma should not be stopped abruptly.

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 of the Bulgarian Drug Agency.

Contact:
8 Damyan Gruev Str.
1303 Sofia
tel.: +359 2 890 34 17
website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Methylprednisolone-Tchaikapharma

Keep out of the reach and sight of children.
Store below 25°C

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

After reconstitution, the solution should be used immediately.

Do not use this medicine if you notice particulate matter or discoloration.

Do not dispose of medicines in the sewers or in the household waste container. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environmen.

6. Contents of the pack and other information

What Methylprednisolone-Tchaikapharma contains
- The active substance is methylprednisolone sodium succinate, equivalent to 40 mg methylprednisolone.

– The other ingredients are:
Powder: sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium hydroxide.
Solvent: Water for injections

What Methylprednisolone-Tchaikapharma looks like and contents of the pack
Each carton contains 1, 3 or 100 vials of powder for solution for injection and 1, 3 or 100 ampoules of solvent for solution for injection.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufactured:
Tchaikapharma High Quality Medicines Inc.
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This leaflet was last revised in: July 2021

For further information on this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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The following information is intended for healthcare professionals only:

Preparation of solutions
To prepare solutions for intravenous infusion, first dissolve methylprednisolone sodium succinate in the indicated manner. Treatment can be started by administering the dissolved methylprednisolone sodium succinate intravenously for at least 5 minutes (e.g. at doses up to 250 mg) and at least 30 minutes (e.g. doses of 250 mg or more). The following doses may be withdrawn and administered in the same way. If necessary, the drug may be administered as divided solutions by adding the reconstituted drug to a 5% aqueous solution of dextrose, saline, dextrose 5% in 0.45% or 0.9% sodium chloride. The resulting solutions are physically and chemically stable for 48 hours.

Instructions for using a two-compartment vial
1. Push down the plastic activator to insert the solvent.
2. Shake gently to aid the dissolution process.
3. Remove the plastic nozzle that covers the center of the stopper.
4. Sterilize the open part of the stopper with a suitable antibacterial agent.

Note: Steps 1 and 4 are required for execution before proceeding.
5. Insert the needle at right angles through the center of the stopper until its tip is slightly visible.
6. Turn the vial down and withdraw the necessary amount.

Parenteral medicinal products should be inspected visually for particulate matter and discoloration prior to administration whenever the solution and the container allow.