

## **Package leaflet: Information for the patient**

### **Methylprednisolon Cortico 16 mg tablets**

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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet**

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

#### **1. What Methylprednisolon Cortico is and what it is used for**

The active substance, contained in Methylprednisolon Cortico, is methylprednisolone. It belongs to a group of medicines called corticosteroids. It is a substance similar to the hormones released by the adrenal glands, known as glucocorticoids. It has strong anti-inflammatory and anti-allergic action. It influences favourably the manifestations of various diseases and conditions resulting from inflammation and allergy.

**Methylprednisolon Cortico** is used for the treatment of symptoms in:

- rheumatic diseases (for example, Bechterew's disease, rheumatoid arthritis in adults and children, inflammation of the joints in psoriasis, gout, etc.)
- lupus erythematosus, inflammation of the skin and muscles, known as dermatomyositis
- seasonal and allergic rhinitis, drug-induced allergies, bronchial asthma

- certain severe skin and eye diseases
- certain blood disorders
- ulcerative colitis and Crohn's disease (inflammation of the large intestine associated with ulcer formation and presenting with severe and persistent bloody diarrhoea and spasms).

It is also used in:

- certain oncological diseases and after organ transplantation (grafting).
- patients in whom, for various reasons, the adrenal glands produce insufficient amounts of hormones and therefore, they need to receive them through the intake of their analogues.

## **2. What you need to know before you take Methylprednisolon Cortico**

### **Do not take Methylprednisolon Cortico:**

- if you are allergic to methylprednisolone or any of the other ingredients of this medicine (listed in section 6);
- if you have severe fungal infections, such as these affecting the lungs or oesophagus.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Methylprednisolon Cortico.

Your doctor will decide the appropriate dose to treat your disease and how long you should take the medicine. Follow closely his/her instructions and do not change the prescribed dose unless explicitly directed by the doctor.

It is particularly important to know that:

- side effects can be avoided or reduced if you take the lowest dose that has a therapeutic effect for the shortest period possible;
- the use of this medicine should not be stopped abruptly, because this may lead to deterioration of your condition and recurrence of the disease;
- normal release of hormones from the adrenal glands is suppressed by a long-term treatment. For enabling the recovery of adrenal gland function, the received daily dose should be reduced gradually. Your doctor will give you precise instructions on how to do this.

It is also important to know that:

- treatment with corticosteroids increases the susceptibility to infections and may also mask some of the signs of an infection.

- varicella (chicken pox) may take a very severe course and result in serious complications in individuals taking corticosteroids for a long time, as these suppress the immunity. It is, therefore, recommended to avoid contacts with people suffering from chicken pox, herpes zoster (shingles) or morbilli (measles).
- vaccination should be avoided. If this is required, you should consult the appropriate specialist.
- in patients with hidden, indiscernible tuberculosis or those with a positive tuberculin test (the so-called Mantoux test), close medical supervision is required to avoid re-activation of the disease.
- the use of methylprednisolone may lead to deterioration of diseases caused by parasites, for example, enterobiasis (a disease caused by parasites known as pinworms).

Before starting your treatment, tell your doctor if you suffer or have suffered from:

- osteoporosis (thinning of the bones and increased susceptibility to fracturing);
- high blood pressure, heart failure (a heart disease that may lead to easy fatigue, shortness of breath, swelling of the ankles), recent myocardial infarction;
- sugar diabetes;
- glaucoma (increased intraocular pressure);
- diseases of the liver (including cirrhosis), kidneys, stomach and intestines (especially, gastric ulcer);
- epilepsy, mental diseases;
- ocular herpes, tuberculosis, abscesses, other suppurative infections;
- myasthenia gravis;
- underactive thyroid gland;
- frequent inflammation of the veins.

You should be acquainted with and your relatives should be informed that during treatment with corticosteroids, there is a risk of developing psychiatric disorders. Most commonly, these are observed within several days to weeks after treatment initiation. Most of them resolve completely after dose reduction or upon treatment discontinuation. This, however, does not remove the need for administration of specific treatment.

If you experience a feeling of depression, anxiety, sleeplessness, lack of motivation or you have suicidal thoughts, you should immediately share this with your relatives and seek a consultation by a medical specialist.

Corticosteroids may lead to delayed growth in children and adolescents; therefore, the treatment should be limited to the lowest dose and for the shortest administration period possible.

In elderly patients, some side effects (osteoporosis, diabetes, high blood pressure, predisposition to infections) may be more frequently observed and more seriously presented, for which intensified medical control is required.

### **Other medicines and Methylprednisolone Cortico**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines accelerate the degradation of corticosteroids, thus reducing their effect. These are rifampicin and rifabutin (antibiotics used to treat tuberculosis), carbamazepine, phenobarbitone, phenytoin (medicines used to treat epilepsy).

Others, such as cimetidine (used to treat heartburn), the antibiotic erythromycin, the antifungal antibiotics ketoconazole, itraconazole, can reduce the degradation of corticosteroids, thus contributing to the enhancement of their effect.

Corticosteroids can:

- reduce the effect of medicines for treating diabetes (including insulin), high blood pressure, diuretics (used to increase the urine output);
- enhance the effect of coumarin anticoagulants (medicines used to reduce blood clotting) and salicylate-containing medicines;

Convulsions have been reported with the concomitant administration of methylprednisolone and cyclosporine (used to reduce the risk of rejection after organ transplantation).

If you are taking digoxin (used to treat heart diseases), periodic medical monitoring is required, since disturbances in water-salt metabolism and loss of potassium may occur.

### **Methylprednisolone Cortico with food, drink and alcohol**

During the treatment with this medicine, you should not consume grapefruit (juice and fruit), since liver degradation of methylprednisolone intensifies and may result in weakening of its therapeutic effect.

### **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

Methylprednisolone crosses the placenta. It is known that in animals, it may cause some congenital defects (for example, cleft lip) and delayed brain growth and development.

There is insufficient evidence that corticosteroids lead to similar effects in humans; during pregnancy, however, corticosteroids should be administered only after a physician's evaluation that the benefit for the mother outweighs the risk for the foetus/newborn.

### Breast-feeding

Corticosteroids are excreted in small amounts in breast milk. During breast-feeding, these should be used only after a physician's evaluation.

### **Driving and using machines**

There is no evidence of unfavourable effects on the ability to drive and use machines.

### **Methylprednisolon Cortico contains lactose monohydrate**

In its composition, the medicinal product contains lactose as an excipient. This makes it unsuitable for patients with a hereditary intolerance to some sugars (lactase insufficiency, galactosaemia or glucose/galactose malabsorption syndrome).

If you have been told by your doctor that you have such intolerance, you should not take this product.

### **3. How to take Methylprednisolon Cortico**

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

#### **Adults**

The daily dose, method and frequency of administration and duration of treatment will be determined by your doctor, in accordance with the type, severity and course of the disease.

The daily dose can be taken once a day or in divided doses, or as a single, but double dose every other day.

It is recommended that the morning dosing of the medicine occurs at about 8:00 A.M.

The tablet can be divided into equal doses.

Side effects can be limited by using the lowest effective dose for the shortest period possible.

In most cases, the treatment is started with a higher dose, which after some time can be reduced or increased, depending on the effect achieved.

You need to know that the discontinuation of the medicine should not be done abruptly in any case.

### **Children**

Dosage in children is determined based on the physician's evaluation. If possible, the daily dose should be administered as a single dose received every other day, and the treatment should be exercised through administering the lowest dose for the shortest period possible.

### **Elderly**

The daily dose, method and duration of administration should be consistent with the higher frequency and severity of side effects in the elderly.

### **If you take more Methylprednisolon Cortico than you should**

In acute overdose with methylprednisolone, no specific manifestations are observed. In chronic overdose, accumulation of fatty tissue in the region of the face, abdomen and hip, formation of striae, redness of the cheek, etc., have been observed. If you have taken a dose higher than the prescribed, ask your doctor for advice.

### **If you forget to take Methylprednisolon Cortico**

If you forget to take a dose, take it as soon as you remember it. Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

### **If you stop taking Methylprednisolon Cortico**

Do not stop taking your medicine if you feel better, unless your doctor has told you. Do not forget that the discontinuation of treatment should not be done abruptly in any case, and should be exercised through gradually reducing the daily dose.

If you stop abruptly the use of the product, it is likely to develop the so-called "withdrawal syndrome" (see section 4).

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

## **4. Possible side effects**

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

Side effects that may occur during the treatment with this medicine include:

### **Common (affects less than 1 in 10 patients)**

- increased susceptibility to and severity of infections, masking of their clinical manifestations, overlay of additional infections
- rounding of the face and persistent redness of the cheeks ("moon face"), excessive hair growth, weight gain
- retention of sodium and water

- increased agitation and carelessness (euphoria), depression and anxiety
- cataract of the eye
- increased blood pressure
- stomach ulcer, sometimes leading to bleeding
- thinning of the skin and acne
- muscle weakness
- growth retardation in children and adolescents
- impaired, delayed wound healing
- low potassium levels in the blood

**Uncommon (affects less than 1 in 100 patients)**

- low blood pressure
- formation of blood clots

**Not known (cannot be estimated from the available data)**

- activation of “dormant” tuberculosis
- increase in the number of white blood cells
- varying in severity allergic reactions
- a need for higher doses of the medicines for the treatment of diabetes
- irritability, mood swings, suicidal thoughts, hallucinations, behavioural changes, agitation, anxiety, confusion
- memory loss, sleep disturbances, seizures, headache, vertigo
- heart failure (a heart disease, which can lead to easy fatigue, shortness of breath, swelling of the ankles, etc.)
- an increase in the intraocular pressure (glaucoma) , damage of the optic nerve, thinning and rupture of the cornea and sclera, exacerbation of ocular viral or fungal infections, persistent protrusion of the eyeballs
- heartburn, nausea, bloating, ulcers of the intestine or oesophagus, fungal infection of the oesophagus, acute inflammation of the pancreas
- formation of striae, dilatation of the skin blood vessels, pinpoint haemorrhages on the skin and mucous membranes
- menstrual irregularities, complete lack of the monthly cycle
- thinning, weakening of the bones and a tendency to spontaneous fractures (osteoporosis) of the vertebrae and long bones, rupture of tendons, muscle weakness, muscle injuries.
- elevation of some laboratory parameters

- suppression of the reaction in skin tests
- suppression of the adrenal function, growth retardation in infants, children and adolescents

### Withdrawal symptoms

A rapid dose reduction upon a long-term treatment can lead to acute adrenal insufficiency, a significant decrease in the blood pressure and death. In the “withdrawal syndrome”, fever, pains in muscles and joints, running nose, conjunctivitis, painful itchy skin nodules and weight loss can also occur.

If any of the side effects gets serious, or if you get any side effects not listed in this leaflet, please ask your doctor or pharmacist.

## **5. How to store Methylprednisolon Cortico**

Store below 25°C.

Shelf-life after first opening the jar: 4 (four) months.

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

Do not use Methylprednisolon Cortico after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not use Methylprednisolon Cortico if you notice changes in the appearance of the tablet.

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 Cortico contains**

- The active substance per tablet is methylprednisolone of 16 mg.
- The other ingredients (excipients) are lactose monohydrate/maize starch (85:15), anhydrous colloidal silica, magnesium stearate.

### **What Methylprednisolon Cortico looks like and contents of the pack**

Round, flat, bevelled tablets with a score line on one side and diameter of 13 mm.

10 (ten) tablets in a blister of transparent, orange PVC/PVDC/Al foil. Two blisters per carton.

40 (forty) tablets in a white, non-transparent plastic jar, closed with a cap with a tamper-evident ring. One jar per carton.

100 (one hundred) tablets in a white, non-transparent plastic jar, closed with a cap with a tamper-evident ring. One jar per carton.

**Marketing Authorisation Holder**

Antibiotic-Razgrad AD  
Office 201, 68 “Aprilsko vastanie” Blvd.  
7200, Razgrad, Bulgaria

**Manufacturer**

Balkanpharma-Razgrad AD  
68 “Aprilsko vastanie” Blvd.  
Razgrad, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Antibiotic-Razgrad AD  
Office 201, 68 “Aprilsko vastanie” Blvd.  
7200, Razgrad, Bulgaria

**This leaflet was last revised in June 2012.**