

## PACKAGE LEAFLET: Information for the user

### METYSOLON

Tablets – 4 mg

(Methylprednisolone)

**Read all of this leaflet carefully before you start taking this medicine.**

- 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 symptoms are the same as yours.
- If you get any side effects or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

#### **In this leaflet:**

1. What Metysolon is and what it is used for?
2. What you need to know before you take Metysolon?
3. How to take Metysolon?
4. Possible side effects
5. How to store Metysolon?
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#### **1. WHAT METYSOLON IS AND WHAT IT IS USED FOR?**

Metysolon contains the active substance methylprednisolone, which is a glucocorticoid (hormone of the adrenal gland) that acts on metabolism, saline balance (electrolytes) and tissue function.

Metysolon is indicated for the treatment of diseases that require systemic therapy with glucocorticoids. These include, depending on the appearance and severity, e.g.:

#### ***Rheumatic diseases***

- active rheumatoid arthritis with severe progressive course forms, e.g. destructively fast running form or extra-articular manifestations;

- arthritis without a known cause in young people (idiopathic juvenile arthritis) with severe forms affecting the internal organs (Still's syndrome) or a non-locally controllable form that affects the eye (inflammation of the iris and the surrounding area, iridocyclitis).

### ***Bronchial and lung diseases***

- bronchial asthma, the concomitant administration of bronchodilator drugs is recommended;
- acute exacerbation of chronic obstructive disease, recommended treatment duration up to 10 days;
- specific lung diseases, such as: acute inflammation of alveoli (alveolitis), pulmonary fibrosis, long-term treatment of chronic forms of sarcoidosis in stages II and III (shortness of breath, cough and deterioration of lung function values).

### ***Diseases of the upper airways***

Severe progressive forms of pollinosis and allergic rhinitis, after failure of intranasally administered glucocorticoids.

### ***Skin diseases***

Skin diseases and mucous membranes, that because of their severity and / or extent or internal organs involvement, are not adequately treated with topical glucocorticoids. These include:

- allergic reactions or those similar to allergic reactions, allergic reactions associated with infections: e.g. acute urticaria, similar reactions to shock (anaphylactic);
- severe skin diseases that damage it partially, drug-induced rash, erythema exudative multiforme, toxic epidermal necrolysis (Lyell's syndrome), erythema nodosum, allergic contact eczema;
- vascular inflammation (vasculitis), e.g. allergic vasculitis, polyarteritis nodosa;
- diseases of the immune system (autoimmune diseases): e.g. dermatomyositis, systemic sclerosis (indurative phase), chronic discoid and subacute cutaneous lupus erythematosus.

### ***Blood diseases / Tumor diseases***

- Blood autoimmune diseases: anemia due to self-destruction of the erythrocytes (autoimmune haemolytic anemia);

- prevention and treatment of vomiting induced by chemotherapy in antiemetic regimens (in combination with other medicinal products).

#### ***Gastrointestinal diseases***

- Ulcerative colitis;
- Morbus Crohn.

#### ***Hormonal replacement therapy***

In case of reduced function of adrenal glands or insufficiency of any etiology (e.g., Addison's disease, adrenogenital syndrome, surgical removal of adrenal glands, reduced function of the pituitary gland) beyond the growth age (drug of first choice are hydrocortisone and cortisone).

Metysolon 4 mg can be used also:

- to suppress the body's defense (immunosuppression) after transplantation in the context of conventional combination therapies,
- as a complementary measure in cytostatic or radiotherapy in existing schemes for combination therapy, palliative therapy (disease-reducing treatment) and antiemetic therapy (treatment against vomiting).

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METYSOLON?**

#### **Metysolon should not be used:**

if you are hypersensitive (allergic) to methylprednisolone, other glucocorticoids or any of the excipients of Metysolon 4 mg.

Except of allergic reactions, there are no contraindications during the short term treatment with Metysolon 4 mg in acute life-threatening situations or when administered as a hormone replacement therapy.

#### **Take special care before you take Metysolon**

Please talk to your doctor or pharmacist before taking Metysolon if higher doses than in hormone replacement therapy are required.

For severe infections Metysolon may only be used in combination with a targeted treatment against the infectious agents.

Metysolon 4 mg should only be used if the doctor considers it necessary for the following diseases. If necessary, at the same time should be taken drugs against the cause of the disease.

- Acute viral infections (e.g. varicella, shingles, herpes-simplex infections, eye cornea inflammation caused by herpes viruses);
- acute and chronic bacterial infections;
- mycotic diseases affecting the internal organs;
- specific diseases caused by parasites (amoeba, worm infections);
- lymph node disease after tuberculosis vaccination;
- if there is tuberculosis in the anamnesis, medicines against it must be taken concomitantly and close medical control is necessary;
- infectious liver inflammation (HBsAg-positive chronic - active hepatitis);
- poliomyelitis;
- about 8 weeks before to 2 weeks after vaccination with live vaccines.

In addition, Metysolon should be taken in the following diseases only if the doctor considers it necessary and if these diseases are treated concomitantly in the appropriate form:

- gastrointestinal ulcers;
- high blood pressure that is stabilized with difficulty;
- severe diabetes mellitus;
- severe loss of bone mass (osteoporosis);
- mental diseases (psychiatric disorders) (even in history);
- increased intraocular pressure (narrow and wide-angle glaucoma);
- ulceration or injury of the eye cornea.

Because of the risk of intestinal perforation and peritonitis, Metysolon should be taken only for necessary medical reasons and under proper supervision in:

- severe colon inflammation (ulcerative colitis) with risk of perforation, abscesses or purulent inflammations;
- inflamed protuberances of the intestinal wall (diverticulitis);
- cases after specific intestinal operations (enteroanastomoses) immediately after surgery.

If you experience blurred vision or other vision problems, contact your doctor.

Signs of peritoneal irritation following gastrointestinal ulcer perforation may be absent in patients receiving high doses of glucocorticoids.

In diabetic patients, the metabolism should be checked regularly; an increased need for the drugs that treat diabetes (insulin, tablets etc.) should be considered.

If you suffer from high blood pressure or severe heart failure, regular medical examinations are necessary because of the risk of deterioration.

Following the use of corticosteroids, the occurrence of a so-called pheochromocytoma crisis has been reported (see section 4. "Possible side effects"), characterized e.g. by a marked increase in blood pressure with headache, sweating, palpitations and paleness of the skin which may possibly be fatal. Corticosteroids should therefore only be used after a reasonable benefit-risk assessment in patients with a suspected or known pheochromocytoma (usually in the adrenal medulla, hormone-forming tumor).

Corticosteroids have been reported to cause blood clots (thrombosis) and vascular occlusions due to venous system blood clots (venous thromboembolism). Please talk to your doctor if you have a condition caused by a blood vessel occluded by a blood clot, or if you are susceptible to it. In these cases, treatment with Metysolon 4 mg should be done with caution. During treatment of a specific muscular paralysis (Myasthenia gravis), a worsening of symptoms may be caused initially that can progress to a myasthenic crisis, which is why the adjustment of Metysolon dose should be performed in hospital. Especially, when face and throat disturbances are severe and breathing is affected, therapy with Metysolon 4 mg should be initiated with extreme caution.

Metysolon may mask the symptoms of infection, complicating this way the diagnosis of an existing or developing infection.

Treatment with a glucocorticoid like Metysolon 4 mg, through immunosuppression, leads to an increased risk of infections by such organisms, which otherwise rarely cause infections (so-called opportunistic germs).

Vaccination with inactivated vaccines is generally possible. However, caution is required when high doses of Metysolon are taken, because the response to vaccine may be impaired. Therefore, vaccination is not recommended in patients receiving maintenance treatment with higher doses (except replacement therapy).

Systemic treatment with glucocorticoids may induce a disease of the choroid and retina of the eye (chorioretinopathy), which may lead to visual disturbances including vision loss.

Prolonged systemic treatment with glucocorticoids may cause chorioretinopathy, even at low doses (see section 4 "Possible side effects").

During long-term therapy with Metysolon regular medical checks are necessary (including eye checks).

Especially during long-term therapy at high doses of Metysolon 4 mg, be careful about sufficient potassium intake (e.g. vegetables, bananas) and salt restricted intake. Check the level of potassium in the blood.

If during treatment with Metysolon special physical stress situations occur, such as: diseases associated with fever, accidents or surgery, inform immediately your doctor or the emergency doctor who will give you information about the continuation of treatment. A temporary increase in the daily dose of Metysolon may be required.

In the long-term treatment with Metysolon 4 mg, your doctor should provide you with a corticosteroid card that you should always carry with you.

Depending on the duration of treatment and posology, a negative impact on calcium metabolism is to be expected, so that osteoporosis prophylaxis is recommended.

This is especially valid when there are co-existing risk factors, such as: familial predisposition, advanced age, insufficient protein and calcium intake, excessive smoking, excessive alcohol consumption, after menopause period and lack of physical activity.

Prevention consists in adequate calcium and vitamin D intake and physical activity. In pre-existing osteoporosis, additional drug therapy should be considered.

Upon termination or possible interruption of long-term administration of Metysolon, the following risks have to be considered:

exacerbation or relapse of the underlying disease, acute adrenal hypofunction (especially in stressful situations, e.g. during infections, after accidents, in increased physical stress), cortisone withdrawal signs and symptoms.

In patients treated with Metysolon, viral diseases could be presented with especially severe forms, sometimes even life-threatening. More risked are immunocompromised children and people without previous chickenpox or measles. If these people have contact with smallpox, measles or shingles-infected persons during treatment with Metysolon, they should immediately go to the doctor to take preventive treatment if necessary.

Rarely, liver and biliary disorders have been reported, most of which regressed after discontinuation of treatment. Therefore, appropriate medical supervision is necessary (see section 4 "Possible side effects").

In patients with hypothyroidism that is not compensated by medication, or liver cirrhosis, comparatively low dosages may be sufficient, and a general dose reduction may be necessary. Careful medical supervision should be provided.

## **Children**

In children, due to the risk of growth retardation, Metysolon should only be used for necessary medical reasons and the growth in height should be checked continuously.

## **Effects of misuse for doping purposes**

The use of Metysolon may give positive results in doping controls. In addition, misuse of Metysolon as a doping agent may endanger your health.

## **Taking Metysolon with other medicines**

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or intend to take / use other medicines, including those taken without a prescription.

### Which other drugs affect the effect of Metysolon?

*Enhancement of the effect and possibly of the side effects:*

- drugs that slow down liver breakdown, such as certain anti-fungal medicines (ketoconazole, itraconazole): the effect of corticosteroids may be increased;
- some female sexual hormones, e.g. for the prevention of pregnancy (pills): the effect of Metysolon can be enhanced;
- some medicines may increase the effects of Metysolon and your doctor may monitor you carefully if you are taking them (including some medicines for HIV: ritonavir, cobicistat)

*Attenuation of the effect:*

- drugs that accelerate the metabolism in the liver [e.g. barbiturates (sleeping drugs), phenytoin, primidone, carbamazepine (antiepileptic drugs), rifampicin (drug against tuberculosis)]: the effect of Metysolon may be decreased;
- ephedrine-containing medicines for mucous membrane swelling: the breakdown of glucocorticoids can be accelerated, and their effectiveness weakened.

*Other possible interactions:*

- medicines used to treat heart disease (e.g. diltiazem [calcium channel blocker]): the degradation of methylprednisolone is slowed down; at the beginning of treatment with Metysolon, medical supervision should be provided; a dose adjustment of methylprednisolone may be required;

- aluminum hydroxide-containing antacids (medicines for the excessive acid production of the stomach) reduce the bioavailability of prednisone. Corresponding studies for methylprednisolone are not available. Interactions cannot therefore not be safely excluded. It is recommended to take the medicines within a time interval of about 2 hours.

**How does Metysolon affect the effect of other drugs?**

*Enhancement of the effect and possibly of the side effects:*

- cardiotonic drugs (cardiac glycosides): their action can be enhanced due to the lack of potassium that Metysolon may cause;
- diuretics and laxatives (saluretics / laxatives): their effect on the elimination of potassium may be enhanced;
- certain drugs that cause muscle relaxation (non-depolarizing myorelaxants): muscle relaxation may last longer (see section 4 “Possible side effects”);

*Attenuation of the effect:*

- drugs that decrease the blood sugar (antidiabetics / insulin): the antidiabetic effect can be reduced;
- anticoagulant drugs (oral anticoagulants that are coumarin derivatives): the anticoagulant effect may be decreased;
- drugs against parasitic diseases (praziquantel): the effect of this drug may be decreased;
- growth hormone (somatropin): its effect may decrease;
- protirelin (hypothalamus hormone): the thyroid stimulating hormone (TSH) increase may be reduced.

*Other possible interactions:*

- anti-inflammatory and anti-rheumatic drugs (salicylates, indomethacin and other non-steroidal anti-inflammatory agents): the risk of peptic ulcers and gastrointestinal bleeding may be increased;
- certain ophthalmologic drugs (atropine) and drugs with similar action (other anticholinergics): additional increase of the intraocular pressure may occur;
- anti-malarial or anti-rheumatic drugs (chloroquine, hydroxychloroquine, mefloquine): there is an increased risk for the occurrence of muscular diseases or heart muscle diseases;

- cyclosporin (drug used for the suppression of the immune system): the blood level of cyclosporin may increase, so there is an increased risk for convulsions;
- certain drugs used to treat high blood pressure (ACE inhibitors): increased risk for the appearance of blood components disorders.

#### Impact on laboratory tests:

Skin response to allergy tests can be suppressed.

#### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

During pregnancy this drug can be taken only with the medical prescription. Experience on the safety of using methylprednisolone in human pregnancy is inadequate.

If Metysolon is used for a long period during pregnancy, possible fetal growth disorders are not excluded. An increased risk of jaw-palate fissuring in human fetuses by the administration of glucocorticoids during the first trimester of pregnancy can not be excluded.

If Metysolon is used at the end of pregnancy, an atrophy of the adrenal glands may appear in the unborn child, which may require treatment after birth.

Glucocorticoids pass into breast milk. If due to the disease higher doses or long-term therapy are required, breast-feeding should be discontinued.

#### **Driving and using machines**

Related to some side effects, such as reduction in visual acuity (due to lens opacification or increase in intraocular pressure), dizziness or headache, Metysolon may in rare cases affect your ability to concentrate and your ability to react. You may not respond quickly enough to sudden and unexpected events. This can be a risk, e.g. if you drive a car or operate machinery. You can then endanger yourselves and others unnecessarily. Please note that alcohol can exacerbate this risk.

#### **Important information about some of the excipients of Metysolon**

This medicine contains lactose. If you have an intolerance to some sugars, contact your doctor before taking Metysolon.

### **3. HOW TO TAKE METYSOLON?**

Always take Metysolon as your doctor has prescribed to you.

The doctor will determine the dose for you individually.

Please follow the instructions of use, otherwise Metysolon may not give you the expected effect.

Ask your doctor or pharmacist if you are not sure.

The posology depends on the nature and severity of the disease and the individual response of the patient. In general, relatively high initial doses are used, which in acute severe forms must be higher than in chronic diseases.

Depending on the clinical symptoms, it can be passed to a low maintenance dose (generally between 4 and 12 mg methylprednisolone daily). Especially in chronic diseases, long-term treatment with low maintenance doses is often required.

The recommended dose is:

#### ***Rheumatic joint diseases***

Initially 4 – 6 tablets Metysolon (16 - 24 mg methylprednisolone) daily, in case of visceral involvement, up to 60 mg of methylprednisolone daily. The target is a maintenance dose that does not exceed 1 1/2 tablets Metysolon 4 mg (equivalent to 6 mg methylprednisolone) daily.

#### ***Bronchial asthma, obstructive airway diseases***

Initially 8 – 10 tablets Metysolon (32 - 40 mg methylprednisolone) daily, dose reduction to 8 mg every 4 days. After 3 - 4 weeks the therapy ends and if necessary, it is passed to inhaled glucocorticoids. Concomitantly the use of bronchodilators (medicines to dilate bronchi) is recommended.

In case of inadequate response, the severe forms of asthma are treated for a long period with the lowest possible dose of 1-2 tablets Metysolon 4 mg (that correspond to 4-8 mg methylprednisolone) daily. The therapy should be circadian, i.e. the total daily dose is taken at once in the morning.

An alternate therapy (taking a two-day dose every other day) is usually not possible. For severe night and early morning symptoms, the daily dose can be divided to 2/3 in the morning and 1/3 in the evening (18.00 - 20.00 o'clock).

## ***Interstitial lung diseases***

### **Acute alveolitis:**

Initially 8 – 10 tablets Metysolon (32 - 40 mg methylprednisolone) daily for one week (divided into 2 doses if needed), then slow dose reduction until conversion to once-daily administration.

### **Pulmonary fibrosis:**

Initially 6 – 8 tablets Metysolon (24 - 32 mg methylprednisolone) daily, possibly in combination with azathioprine or penicillamine. Slow dose reduction to individual maintenance dose of 1-2 tablets Metysolon 4 mg (equivalent to 4 - 8 mg methylprednisolone) daily.

### **Sarcoidosis:**

Initially 8 – 10 tablets Metysolon (32 - 40 mg methylprednisolone) daily till the onset of the effect, divided in two doses if needed. Reduction of therapy within 4 - 6 weeks, till to once-daily administration. Chronic forms of stages II and III require long-term therapy with daily doses of 2 - 3 tablets Metysolon 4 mg (equivalent with 8 – 12 mg methylprednisolone), where an alternating administration (taking a two-day dose every other day) should be preferred.

## ***Pollinosis, allergic rhinitis***

In addition to antihistamines and locally prophylactic and antiallergic agents, when they are not sufficiently effective or there is a risk of involvement of medium and small airways: short-term therapy with initially 4 tablets Metysolon (16 mg methylprednisolone) daily, in the morning, for 4 days (only in specific cases higher initial doses are required). Dose reduction to 2 tablets Metysolon 4 mg (equivalent to 8 mg methylprednisolone) daily for an additional 4 days.

Cessation of therapy after 8 days, in case of insufficient response, treatment may continue for 1 - 2 weeks with 1-2 tablets Metysolon 4 mg (equivalent to 4-8 mg of methylprednisolone) daily.

## ***Skin disorders***

Depending on the severity and appearance form, 80-160 mg methylprednisolone daily may be indicated initially. The dose reduction is rapid, so that the therapy ends in general after 2 - 4 weeks. Only in a few cases, a prolonged therapy over weeks and months is necessary.

### ***Autoimmune disorders***

Depending on the severity and organ involvement, initially 40 - 160 mg methylprednisolone daily, then slow reduction till to the maintenance dose, which may be required over many years. In acute forms, initial high-dose therapy may be necessary.

### ***Blood disorders (autoimmune hemolytic anemia)***

Initially 80 - 160 mg methylprednisolone daily, after the response to treatment (usually within 2 weeks) the dose is slowly reduced to the maintenance dose.

### ***Ulcerative colitis and Morbus Crohn***

Initially 40 - 80 mg of methylprednisolone daily, then the dose is slowly reduced. In ulcerative colitis, the treatment should be ended as soon as possible. If long-term therapy is required in Crohn's disease, alternate therapy should be considered.

### ***Replacement therapy in the adrenal glands insufficiency***

1 - 2 Metysolon 4 mg tablets (equivalent to 4 - 8 mg methylprednisolone) daily, associated with a mineralocorticoid if needed.

### ***Immunosuppression after transplantation in conventional combination therapies***

The dosage is according to the immunosuppressive protocol used. The clinical situation determines the total dose reduction or the need for a maintenance dose.

### ***Supplementary measure for cytostatic or radiotherapy in existing schemes for combination therapy, palliative or antiemetic therapy***

The dosage is carried out according to the tumor protocol or antiemetic scheme used. The clinical situation determines the total dose reduction or the need for a maintenance dose.

Usually take the tablets (all the daily dose) during or after breakfast (between 6.00 and 8.00 o'clock), whole, with sufficient liquid, e.g. a glass of water (circadian therapy).

If clinically supported, with the doctor instruction, the drug may be taken every two days.

The duration of treatment depends on the course of the disease.

Once a satisfactory treatment result is achieved, the dose is reduced to a maintenance dose or treatment is stopped. To do this, your doctor will determine a treatment regimen that you should follow exactly.

The hormone replacement therapy for chronic adrenocortical dysfunction is lifelong.

### **If you take more Metysolon than you should**

Generally, Metysolon is tolerated without complications even when it is taken in high doses for a short period of time. It is not necessary to take any special action. If you notice enhanced side effects or other side effects, consult your doctor.

### **If you forget to take Metysolon**

You may take the forgotten dose during the day and the other day continue to take the prescribed dose by the doctor. If you have forgotten to take the dose more than once, it may occur among others that the disease returns or it worsens. In such cases you have to consult with your doctor, who will check the treatment and if needed may adjust it.

Do not take a double dose if you have forgotten to take a dose.

### **If you stop taking Metysolon**

Always follow the dosage scheme prescribed by the doctor. Metysolon should not be discontinued arbitrary, because long term treatment with Metysolon leads to the reduction of the glucocorticoids produced by the body. A severe situation of physical stress may be life threatening (Addison's syndrome).

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Metysolon may cause side effects, although not everybody gets them.

For the evaluation of side effects, the following frequency indicators are used:

Very common	May affect more than 1 in 10 patients
Common	May affect up to 1 in 10 patients
Uncommon	May affect up to 1 in 100 patients
Rare	May affect up to 1 in 1.000 patients
Very rare	May affect up to 1 in 10.000 patients
Unknown	Frequency cannot be estimated from the available data.

The following side effects are listed without frequency, that is, the frequency is unknown (frequency cannot be estimated from the available data).

### ***Hormone replacement therapy***

The risk of adverse effects is low if the recommended doses are followed.

### ***In the treatment of some diseases, when higher doses than in the hormone replacement therapy are used:***

Depending on dose and duration of therapy, the following side effects may occur:

#### **Blood and lymphatic system disorders**

Blood components disorders (increase of the number of white blood cells, red blood cells or platelets, decrease of some types of the white blood cells).

#### **Immune system disorders**

Weakening of the immune system with increased risk of infections (certain virus-related diseases, such as chickenpox, cold sores [herpes simplex] or - during the viremic phase - shingles, can have a serious, sometimes life-threatening course), exacerbation of latent infections, masking of infections symptoms, allergic reactions.

#### **Endocrine disorders**

Pheochromocytoma crisis (e.g., high blood pressure with headache, sweating, palpitations, and pale skin in the presence of a pheochromocytoma, see section 2 "Take special care with Metysolon"), appearance of Cushing's syndrome (typical symptoms: moon face, truncal obesity, and face redness), inactivity or atrophy of the adrenal glands cortex, growth retardation in children, disorders of sexual hormones (lack of menstruations, hirsutism, impotence).

#### **Metabolism and nutrition disorders**

Deposition of lipids in different parts of the body, e.g. in the spinal canal (epidural) or chest (epicardial, mediastinal).

Increased blood sugar, diabetes, increased lipids in blood (blood cholesterol and triglycerides), fluid accumulation in the tissues (sodium retention with edema formation),

possible potassium deficiency (caution: arrhythmias!) due to its increased elimination, increased protein degradation.

#### Psychiatric disorders

Severe depression, irritability, personality disorders, euphoria, mood swings, increased drive and appetite, psychosis, sleep disorders.

#### Nervous system disorders

Increased intracranial pressure (especially in children), manifestation of latent epilepsy and increase of the susceptibility to convulsions if there is a known epilepsy, dizziness, headache.

#### Eye disorders

Increase of the inner eye pressure (glaucoma), lens opacity (cataract), disease of the retina and the choroid of the eye (chorioretinopathy, see section 2 "Take special care with Metysolon"), worsening of corneal ulcers, favoring of the inflammation caused by viruses, bacteria or fungi, blurred vision.

#### Cardiac disorders

Increased pulmonary congestion in patients with heart failure.

#### Vascular disorders

Hypertension, increased blood clotting (thrombotic events), increased risk for atherosclerosis and thrombosis, blood vessels inflammation (also as withdrawal syndrome after long-term treatment).

#### Gastrointestinal disorders

Gastrointestinal ulcers with the risk of perforation (with e.g. peritonitis), gastrointestinal bleeding, pancreatitis, epigastric discomfort.

#### Hepatobiliary disorders

Elevation of liver enzymes (see section 2 "Take special care with Metysolon").

### Skin and subcutaneous tissue disorders

Stretch marks, skin thinning ("parchment skin"), dilation of skin vessels, increased capillary fragility, tendency to bruising, small underskin hemorrhages in the form of pinpoints or spots, increase of body hair growth, acne, delayed wounds healing, inflammatory alterations on facial skin, especially in the mouth, nose and eyes, changes in skin pigmentation, hypersensitivity reactions, e.g. rash.

### Musculoskeletal and connective tissue disorders

Muscle atrophy and weakness, in myasthenia gravis reversible increase in muscle weakness, which may progress to a myasthenic crisis, trigger of an acute myopathy (muscle disease) if there is additional use of non-depolarizing muscle relaxants (see section 2 "Taking Metysolon with other medicines"), loss of bone mass (osteoporosis) is dose-dependent and is possible also with only short-term use, in severe cases with the risk of bone fractures, other forms of bone mass loss (aseptic bone necrosis on the head of the humerus and femur), tendon rupture.

Note: In case of too rapid dose reduction after long-term treatment, symptoms like muscle and joint pain may appear.

### Investigations

Weight gain.

### **Special Instructions**

Please talk to your doctor if any of the side effects disturb you or if you notice other side effects during treatment with Metysolon. Do not interrupt the treatment yourself in any case. If you experience gastrointestinal disturbances, back pain, shoulder or hips pain, mental disturbances, abnormal blood sugar variation in diabetics, or other disturbances, inform your doctor immediately.

## **5. HOW TO STORE METYSOLON?**

Keep out of the reach and sight of children!

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the package.

## **6. FURTHER INFORMATION**

### **What Metysolon 4 mg tablets contain**

The **active substance** is methylprednisolone.

1 tablet contains 4 mg methylprednisolone.

The excipients are: partially pregelatinized starch, maize starch, lactose monohydrate, colloidal anhydrous silica, sodium starch glycolate, magnesium stearate.

### **Contents of the pack**

Box with 10 tablets.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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