

**Package leaflet: information for the user****Metamizol Slavia 500 mg tablets**

Metamizole sodium monohydrate

Metamizol Slavia may cause an abnormally low number of white blood cells (agranulocytosis), which may lead to serious and life-threatening infections (see section 4).

You must stop taking the medicine and contact your doctor immediately if you develop any of the following symptoms: fever, chills, sore throat, painful lesions in the nose, mouth and throat or in the genital or anal region.

If you have ever had agranulocytosis during treatment with metamizole or similar medicines, you must never take this medicine again (see section 2).

**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 additional questions, ask your physician or pharmacist.
- This medicine has been described only for you. You should not give it to other people. It can harm them, even if they present the same disease symptoms as you.
- If you experience any adverse reactions, contact your physician, pharmacist or nurse. These include any possible adverse reactions not mentioned in this leaflet. See section 4.

**What is in this leaflet**

1. What Metamizol Slavia is and what it is used for
2. What you need to know before you use Metamizol Slavia
3. How to use Metamizol Slavia
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**1. What Metamizol Slavia is and what it is used for**

Metamizol Slavia contains metamizole sodium monohydrate, which is a pain-relieving medicine (analgesic) belonging to the group of medicines called pyrazolones.

Metamizol Slavia also has antispasmodic and antipyretic (fever-reducing) effects.

It is used for the treatment of severe acute or persistent pain and high fever that does not respond to other treatments.

This medicine is intended for adults and adolescents aged 15 years and older.

If you do not feel better or if you feel worse, you must talk to a doctor.

**2. What you need to know before you use Metamizol Slavia****Do not take Metamizol Slavia if:**

- you are allergic to metamizole or any of the other ingredients of this medicine (listed in section 6);
- you have a history of allergy to pyrazolone derivatives (for example phenazone, propyphenazone) or pyrazolidines (for example phenylbutazone, oxyphenbutazone) (medicines used for the treatment of pain and inflammation);

- you have previously had a significant decrease in one type of white blood cells called granulocytes caused by metamizole or any similar medicines called pyrazolones or pyrazolidines;
- you have bone marrow problems or you have a condition affecting the way blood cells are produced or function;
- you have a blood formation disorder (impairment of the haematopoietic system);
- you have a significant decrease in the number of white blood cells (leukocytes) in the blood (< 1500/mm<sup>3</sup>);
- you have previously had bronchospasm or other allergic reactions (for example urticaria, rhinitis, swelling of the lips, face, throat and tongue with difficulty breathing and swallowing) induced by analgesic medicines such as salicylates (acetylsalicylic acid), paracetamol, diclofenac, ibuprofen, indometacin or naproxen;
- you have a rare metabolic disorder called acute intermittent hepatic porphyria (an inherited condition with risk of destruction of red blood cells);
- you have congenital glucose-6-phosphate dehydrogenase deficiency (risk of destruction of red blood cells);
- you have severe renal, hepatic or cardiac failure;
- you are in the last three (3) months of pregnancy (see section 2, 'Pregnancy, breast-feeding and fertility').

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Metamizol Slavia if:

- you notice signs and symptoms suggesting a blood disorder (for example, general weakness, infection, persistent fever, bruising, bleeding, pallor), consult a doctor immediately. It may be a condition called pancytopenia (reduction in the number of all types of blood cells).
- you have any of the following conditions, because these carry an increased risk of severe anaphylactoid reactions to metamizole:
  - asthma accompanied by inflammation of the nasal mucosa;
  - long-standing/permanent urticaria;
  - hypersensitivity to colorants (for example, tartrazine) or preservatives (for example, benzoates);
  - hypersensitivity to alcohol, meaning that you react even to a small amount of alcoholic drinks with sneezing, watering eyes and marked facial flushing.
- you have low blood pressure, have fluid loss, have unstable fluid volume in the body or incipient circulatory failure, or you have a high fever. In these cases, there is an increased risk of severe hypotensive reactions (reactions associated with low blood pressure). Administration of metamizole must be considered with particular caution and, if metamizole is given under these circumstances, careful medical supervision is required. Preventive measures are needed to reduce the risk of a severe hypotensive reaction. Administration of metamizole may induce hypotensive reactions that are not related to the diseases mentioned above. These reactions appear to be dose-dependent.
- you have severe disease of the arteries of the heart or the blood vessels supplying the brain are significantly narrowed. In these cases, it is absolutely essential to avoid a drop in blood pressure; therefore metamizole must be administered only with careful monitoring of circulatory functions.
- you have kidney or liver disease. In this case, you should not be given high doses of metamizole because its elimination from the body is reduced.
- you are to undergo any laboratory test, because metamizole may affect the results of some tests (for example, blood creatinine concentrations, fats, HDL cholesterol or uric acid).

Stop taking the medicine and contact your doctor immediately if any signs or symptoms suggesting blood disorders occur during administration of Metamizol Slavia, such as malaise, infection, persistent fever, bruising, bleeding or pallor.

### **Abnormally low number of white blood cells (agranulocytosis)**

Metamizol Slavia may cause agranulocytosis, a very low number of one type of white blood cells called granulocytes, which are important in fighting infection (see section 4). You must stop taking metamizole and seek medical advice immediately if you develop the following symptoms, as this may indicate possible agranulocytosis: chills, fever, sore throat and painful lesions of the mucous membranes (moist body surfaces), especially in the mouth, nose and throat or in the genital or anal region. Your doctor will perform a laboratory test to check your blood cell count.

If metamizole is used to reduce fever, some early symptoms of agranulocytosis may go unnoticed. In addition, these symptoms may also be masked if you are being treated with antibiotics. Agranulocytosis may occur at any time during the use of Metamizol Slavia and even shortly after you stop taking metamizole.

You can develop agranulocytosis even if you have used metamizole without problems in the past.

#### Severe skin reactions

Severe skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), have been reported in association with treatment with metamizole. Stop treatment with metamizole and seek medical attention immediately if you notice any of the symptoms associated with these severe skin reactions described in section 4.

If you have ever developed severe skin reactions, you must never restart treatment with Metamizol Slavia (see section 4).

#### Liver problems

Inflammation of the liver has been reported in patients taking metamizole, with symptoms appearing within a few days to a few months after starting treatment.

Stop taking Metamizol Slavia and contact a doctor if you have symptoms related to liver problems such as nausea or vomiting (feeling sick), fever, tiredness, loss of appetite, dark-coloured urine, pale-coloured stools, yellowing of the skin or the whites of the eyes, itching, rash or pain in the upper part of the stomach. Your doctor will check your liver function.

You should not take Metamizol Slavia if you have previously taken any medicine containing metamizole and had liver problems.

#### **Children and adolescents**

Metamizol Slavia must not be given to children and adolescents under 15 years of age.

#### **Metamizol Slavia with other medicines**

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

- ciclosporin (a medicine used to suppress the body's immune response). Metamizol Slavia may decrease the concentration of ciclosporin in the blood; this should be monitored if the two medicines are used together, together with blood creatinine values;
- methotrexate (a medicine used in the treatment of cancer or a rheumatic disease), because it may increase the blood toxicity of methotrexate, especially in the elderly;
- other medicines with toxic effects on the bone marrow (myelotoxic medicines). You must not take Metamizol Slavia together with these medicines;
- acetylsalicylic acid (even in low doses, given for heart protection), because this medicine may reduce the effect of acetylsalicylic acid in preventing platelet aggregation. Therefore, caution is required;
- captopril, a medicine used for the treatment of high blood pressure;
- lithium, a medicine used to treat and prevent manic episodes in people with bipolar disorder;
- bupropion, a medicine used to treat depression or to help stop smoking;
- efavirenz, a medicine used to treat HIV/AIDS;
- methadone, a medicine used to treat addiction to illicit drugs (so-called opioids);
- valproate, a medicine used to treat epilepsy or bipolar disorder;
- tacrolimus, a medicine used to prevent organ rejection in transplant patients;
- sertraline, a medicine used to treat depression;
- triamterene, a medicine used as a diuretic;
- other antihypertensives and diuretics (except furosemide). Metamizol Slavia may change their effect.

Metamizole Slavia interferes with laboratory tests that use the Trinder reaction or similar reactions (for example tests for measuring serum values of creatinine, triglycerides, HDL cholesterol and uric acid).

#### **Metamizol Slavia with food, drinks and alcohol**

Metamizol Slavia may be taken with liquids. Consumption of alcoholic drinks during treatment with Metamizol Slavia should be avoided, because it may increase the effect of ethyl alcohol.

### **Pregnancy, breastfeeding 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

Available data on the use of metamizole during the first three (3) months of pregnancy are limited, but do not indicate harmful effects on the embryo. In certain cases, if there are no other treatment options, administration of a single dose of metamizole during the first (1-3 months) and second trimester (3-6 months) of pregnancy may be acceptable, after you have discussed this with your doctor or pharmacist and after the benefits and risks of using metamizole have been carefully assessed. However, in general, the use of metamizole during the first or second trimester of pregnancy is not recommended.

During the last three (3) months of pregnancy, you must not take Metamizol Slavia because of an increased risk of complications in both the mother and the child (bleeding, premature closure in the unborn child of an important blood vessel, called the ductus Botalli, which normally closes only after birth).

You must not use Metamizol Slavia if you are in the first or last trimester of pregnancy, because it may affect the unborn child. In the second trimester of pregnancy, you may use Metamizol Slavia only on your doctor's recommendation, if he/she considers the treatment absolutely necessary, in the lowest possible doses and for the shortest possible period.

#### Breastfeeding

Metabolites of metamizole pass into breast milk in considerable amounts and a risk to the breast-fed child cannot be excluded. Therefore, repeated administration of metamizole in particular should be avoided during breast-feeding. In the case of a single dose of metamizole, mothers are advised to collect and discard breast milk for 48 hours after administration of the dose.

### **Driving vehicles and use of machineries**

When administered at the recommended doses, Metamizol Slavia has no effect on the ability to drive or use machines. However, when administered in high doses, Metamizol Slavia may affect the ability to concentrate and react, which constitutes a risk of accidents, especially if associated with the consumption of ethyl alcohol. If you notice balance disturbances or a spinning sensation after taking this medicine, avoid potentially dangerous activities such as driving vehicles and using machines.

Metamizol Slavia contains **sugar and 32.7 mg sodium in each tablet**. This amount of sodium is equivalent to 1.6% of the recommended maximum daily sodium intake for an adult.

### **3. How to use Metamizol Slavia**

Always use this medicine exactly as your physician, pharmacist or nurse has told you. Talk to your physician, pharmacist or nurse if you are not sure.

The tablets should be swallowed whole, preferably after meals.

#### **Recommended dose**

The dose depends on the intensity of the pain or fever and on individual sensitivity in response to Metamizol Slavia.

The lowest dose needed to control pain and fever should always be chosen. Your doctor will tell you how to take Metamizol Slavia.

#### Adults and adolescents aged 15 years and over (weighing more than 53 kg)

The recommended dose is 1-2 tablets (equivalent to 500-1000 mg metamizole sodium monohydrate), which may be administered up to 4 times a day at intervals of 6-8 hours.

The maximum daily dose is 4000 mg (corresponding to 8 Metamizol Slavia tablets).

A clear effect can be expected 30 to 60 minutes after oral administration.

#### Children and adolescents under 15 years of age

Metamizol Slavia must not be used in children and adolescents under 15 years of age. Other pharmaceutical forms and strengths of this active substance are available for younger children; ask your doctor or pharmacist.

#### Patients with renal or hepatic impairment

Since the elimination rate is reduced in patients with renal or hepatic impairment, repeated high doses should be avoided. No dose reduction is necessary when it is administered only for a short period of time. There is no experience regarding long-term use. Do not use Metamizol Slavia for a prolonged period.

#### Elderly patients and patients in poor general health/with renal impairment

In the elderly, in patients in poor general health and in those with reduced kidney function, the dose should be reduced because the elimination of metamizole metabolites may be delayed.

#### **If you take more Metamizol Slavia than you should**

If you have taken more Metamizol Slavia than the recommended dose, contact your doctor immediately or go to the emergency department of the nearest hospital.

Acute intoxication is manifested by gastrointestinal disorders (nausea, vomiting, abdominal pain), impairment of kidney function/acute renal failure and, rarely, symptoms affecting the central nervous system (vertigo, dizziness, drowsiness, coma, convulsions), decreased blood pressure up to shock and disturbances of heart rhythm (rapid heartbeat).

After administration of very high doses, elimination of a non-toxic metabolite of metamizole (rubazonic acid) may cause red discoloration of the urine.

#### **If you forget to take Metamizol Slavia**

Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Metamizol Slavia**

Metamizol Slavia is used only when needed. You can stop treatment as soon as you feel well.

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

#### **4. Possible adverse reactions**

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

**Stop using metamizole and seek medical attention immediately if you notice any of the following serious side effects:**

- Allergic reactions (anaphylactoid or anaphylactic reactions) - rare adverse reaction. Typical signs of mild reactions include symptoms such as burning eyes, cough, nasal symptoms, nasal congestion, chest pain, reddening of the skin (especially on the face and head), urticaria and swelling of the face and - rarely - nausea and stomach cramps. Special warning symptoms are burning, itching and a feeling of heat on and under the tongue and, especially, on the palms of the hands and soles of the feet. Such mild reactions may progress to more severe forms with severe urticaria, severe angioedema (swelling, including in the laryngeal area), severe bronchospasm (spasmodic constriction of the lower airways), increased heart rate (sometimes pulse too slow), cardiac arrhythmias, marked fall in blood pressure (sometimes preceded by a rise in blood pressure), loss of consciousness and circulatory shock. These reactions may occur even after several administrations not accompanied by complications and may be life-threatening and even fatal in some cases. In patients with analgesic-induced asthma syndrome, hypersensitivity reactions usually manifest similarly to asthma attacks (see section 2).
- Reddish, flat, target-like or circular patches on the trunk, often with central blisters; peeling of the skin, ulcers of the mouth, throat, nose, genitals and eyes. These serious skin rashes may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- Feeling sick (nausea or vomiting), fever, tiredness, loss of appetite, dark urine, pale stools, yellowing of the skin or the whites of the eyes, itching, rash or stomach pain. These symptoms may be signs of liver problems. See also section 2 'Warnings and precautions'.
- Severe decrease in the number of certain white blood cells (agranulocytosis), including cases with fatal outcome, or decrease in the number of platelets (thrombocytopenia) - rare adverse reactions. These reactions are probably immunological. They may also occur when metamizole has previously been given without complications.

A severe decrease in the number of white blood cells may manifest itself by fever (even persistent or

recurrent), chills, sore throat, difficulty swallowing, inflammation of the mouth and throat mucosa, as well as of the genital and perianal area. In patients receiving concomitant antibiotic treatment, the signs and symptoms characteristic of a significant decrease in white blood cells may be minimal. The erythrocyte sedimentation rate (a blood test) is greatly increased, while enlargement of lymph nodes is usually slight or absent. For recovery, immediate discontinuation of treatment is of decisive importance. Therefore, if the signs and symptoms listed occur, treatment must be stopped immediately.

Kounis syndrome - acute coronary syndromes associated with severe allergic reactions - has been reported.

After administration of Metamizol Slavia, a transient decrease in blood pressure may occasionally occur (without other signs and symptoms characteristic of a severe allergic reaction); in rare cases, this fall may progress to critical hypotension.

Asthma attacks have been reported, especially in patients with hypersensitivity to acetylsalicylic acid. At high doses, breathing may become deeper and more frequent.

With unknown frequency (cannot be estimated from the available data), inflammation of the liver, yellowing of the skin or whites of the eyes, and increased values of liver enzymes in the blood may occur.

Occasionally, a skin eruption at the same site each time the medicine is administered (fixed drug eruption) may occur. Rarely, rash may occur.

In very rare cases, acute deterioration of kidney function (acute renal failure) may occur, in some cases associated with reduced urine volume, absence of urine, protein in the urine, especially when there is a history of kidney disease. In isolated cases, acute interstitial nephritis (inflammation of the kidneys) may occur.

Red discoloration of the urine may occur due to the presence in low concentration in the urine of one of the metabolites of Metamizole Slavia: rubazonic acid.

### **Adverse reactions reporting**

If you present any adverse reactions, please address your physician or pharmacist. Those include any adverse events that are not mentioned in this leaflet. Also, you can report adverse reactions through the national reporting system, detailed and published on the National Agency for Medicines and Medical Devices of Romania <http://www.anm.ro/>. By reporting the adverse reactions, you can contribute to the provision of additional information regarding the safety of this medicine.

National Agency for Medicines and Medical Devices of Romania,  
48 Aviator Sănătescu Street, 1<sup>st</sup> District,  
Bucharest 011478-RO,  
Phone: +4 0757 117 259,  
Fax: +4 0213 163 497,  
E-mail: [adr@anm.ro](mailto:adr@anm.ro)

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

## **5. How to store Metamizol Slavia**

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

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

This medicine does not require any special storage conditions.

### **EXPIRED AND/OR UNUSED MEDICINES MUST BE RETURNED TO PUBLIC OR PRIVATE HOSPITALS.**

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. Package contents and other information**

### **What does Metamizol Slavia contain**

- The active ingredient is metamizole sodium monohydrate. Each tablet contains 500 mg metamizole sodium monohydrate.
- Other ingredients: sugar, maize starch, magnesium stearate.

### **What Metamizol Slavia looks like and package composition**

Round, biconvex, white to almost white tablets, with a diameter of 12 mm.

Box with 1 white PVC-PVDC/Al blister containing 10 tablets

Box with 2 white PVC-PVDC/Al blisters each containing 10 tablets

Box with 3 white PVC-PVDC/Al blisters each containing 10 tablets

Not all pack sizes may be marketed.

### **Marketing authorization holder and manufacturer**

#### **Marketing authorization holder**

Slavia Pharm SRL

44C Theodor Pallady Blvd.

District 3, postal code 032266, Bucharest, Romania

**This leaflet was revised in June 2025.**

Detailed information on this medicine is available on the website of the National Agency for Medicines and Medical Devices of Romania: <http://www.anm.ro/>