



# Spasmobloc 500 mg/5 mg/0,1 mg tablets

*Metamizole sodium/Pitofenone hydrochloride/Fenpiverinium bromide*

## Read this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet, or as directed by your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- If you need more information or advice, ask your pharmacist.
- If you experience any side effects, tell your doctor or pharmacist. This includes all possible side effects not listed in this leaflet. See point 4.
- You should talk to your doctor if you don't feel better or feel worse after three days.

### In this leaflet:

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

#### 1. What is Spasmobloc and what it is used for

Spasmobloc is a combined product that combines analgesic and relaxing smooth muscle action. Spasmobloc is applied for the symptomatic treatment of mild or moderate pain syndrome spasm of smooth muscles of internal organs in the stomach or intestinal colic, biliary colic, renal colic renal stone disease, painful menstruation (dysmenorrhea).

#### 2. What you should know before taking Spasmobloc

**Do not take Spasmobloc** in the following cases:

- if you are allergic (hypersensitive) to any of the active substances and / or any of the excipients;
- hypersensitivity to pirazolone derivatives or other NSAIDs;
- at the gastro-intestinal obstruction and megacolon (an extension of the colon);
- difficulty in emptying due to muscle weakness (atony) and gall bladder;
- with severe hepatic or renal impairment;
- in some hereditary diseases (glucose-6-phosphate dehydrogenase and porphyria);
- in certain blood diseases - leukopenia (reduction in the total number of leukocytes), agranulocytosis (severe reduction or complete absence of certain white blood cells, granulocytes), aplastic anemia (anemia due to impaired haematopoietic bone marrow function);
- angle closure glaucoma (acute glaucoma characterized by the fact that the eye pressure increases rapidly);
- pregnancy and lactation.

#### Warnings and Precautions

Talk to your doctor or pharmacist before taking Spasmobloc.

The product is used with caution in patients with impaired renal and / or hepatic function disorders associated with narrowing of the gastrointestinal tract and difficult passage of gastrointestinal contents (achalasia, pyloroduodenal stenosis), gastroesophageal reflux disease, intestinal atony, paralytic ileus, glaucoma (increased eye pressure), myasthenia gravis (muscle

weakness), heart disease (arrhythmias, ischemic heart disease, congestive heart failure) in hypersensitivity to nonsteroidal anti-inflammatory, analgesic and antirheumatic drugs (analgesics intolerance) as to other medications or food or other allergy (hay fever, asthma).

With prolonged ingestion (more than 7 days) is necessary to control the peripheral blood picture and the functional state of the liver.

Metabolites of Metamizole can color urine red, which has no clinical significance.

#### Other medicines and Spasmobloc

Tell your doctor or pharmacist if you are taking, have recently taken or may take other medicines. Concomitant use of Spasmobloc with other medicines can strengthen or weaken their effects:

- metamizol increases the content of antiparasitic agent chloroquine in the blood reduces the effects of coumarin anticoagulants (products reduce blood clotting) and cyclosporine;
- tricyclic antidepressants, oral contraceptives and allopurinol, slow metabolism of metamizol and increase toxicity;
- barbiturates, glutethimide, phenylbutazone (products that enhance degradation of liver function) may reduce the effects of metamizol;
- calming nervous system drugs (tranquilizers and sedatives) reinforce the analgesic effect of Spasmobloc;
- concomitant use of Spasmobloc with other antipyretic, analgesic and anti-inflammatory drugs increase the risk of allergic reactions;
- co-administration of Spasmobloc with chloramphenicol and other myelotoxic products can cause risk of suppression of bone marrow function;
- co-administration of metamizol with chlorpromazine and other phenothiazine derivatives have an increased risk of decreased body temperature
- metamizole decreases plasma concentrations of Cyclosporin A and can threaten the tissue or organ transplantation

#### Spasmobloc with food, beverages and alcohol

You should avoid alcohol during treatment with the product.

#### Pregnancy and breast-feeding

Please consult your doctor or pharmacist before taking any medicine.

#### Pregnancy

Spasmobloc is not administered during pregnancy.

#### Breast-feeding

The product passes into breast milk and is not recommended during lactation.

#### Driving and using machines

It should be used with caution in people who drive or operate machinery since continued acceptance of Spasmobloc may appear dizziness and disorder accommodation (the ability of the eye for seeing near and far).

#### Spasmobloc contains wheat starch and lactose

In the composition of the product is contained as an excipient wheat starch, which makes it unsuitable for patients with gluten enteropathy (congenital disorder of the small intestine, manifested by diarrhea in the use of wheat products).

This medicinal product contains lactose as an ingredient, which makes it unsuitable for patients with lactose intolerance.

### 3. How to take Spasmobloc

Always take this medicine exactly as described in this leaflet, or as directed by your doctor, or pharmacist. If you're not sure, ask your doctor or pharmacist.

Recommended daily dose:

#### Adults and children over 15 years:

- 1-2 tablets, 2 - 3 times daily.

Maximum daily dose - 6 tablets

#### Use in children

- Children at age from 12 to 15 years – 1 tablet 2-3 times a day. Maximum daily dose - 3 tablets.

- Children at age from 9-12 years - ½ tablet 2-3 times daily. Maximum daily dose - 2 tablets.

The tablets are taken by mouth with water after eating.

The duration of treatment should not exceed 3 days.

#### If you take more Spasmobloc than you should

When taking a higher dose than prescribed, you should consult a doctor for help!

Your doctor will decide what action to take, if needed.

In case of overdose is most commonly seen allergic reactions, nausea, vomiting, dizziness, tinnitus, shock, acute renal and liver failure, seizures.

The first steps in overdose are emesis, gastric lavage, followed by symptomatic treatment. There is no specific antidote.

#### If you forget to take Spasmobloc

If you miss a dose, take the medicine at the next regular intake without increasing the dose.

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

#### If you stop taking Spasmobloc

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 Spasmobloc can cause side effects, although not everybody gets them.

Adverse reactions are divided into groups according to the terminology of the Medical Dictionary for Regulatory Activities (MedDRA) together with the corresponding frequency:

- Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare ( $\geq 1/10,000$  to  $<1/1,000$ ) very rare ( $<1/10,000$ ), not known (data can not be estimated).

Adverse reactions with Spasmobloc are most often temporary and resolved with discontinuation. In some patients may occur:

Blood and lymphatic system disorders - changes in the number of blood cells (agranulocytosis, thrombocytopenia, leukopenia - a decrease platelets or leukocytes);

Immune system disorders - rash, urticaria, pruritus, rarely severe allergic reactions - bronchospasm (shortening of smooth muscle in the walls of the bronchi), angioedema (swelling of face, lips, eyelids and some mucous membranes), rarely anaphylactic shock;

Nervous system disorders - dizziness;

Eye disorders - visual disturbances;

Cardiac disorders - a rare feeling of palpitations, rapid heart rate, irregular heart beat;

Vascular disorders - low blood pressure;

Respiratory, thoracic and mediastinal disorders - bronchospasm;

Gastrointestinal disorders - discomfort, dry mouth, constipation, exacerbation of gastritis or peptic ulcer disease;

Skin and subcutaneous tissue - rarely, skin allergies and rashes, Lyle syndrome or Stevens-Johnson syndrome (severe blistering);

Renal and urinary disorders - difficulty urinating, decreased or increased amount of urine, inflammation of the kidneys.

If any of the side effects gets serious, or if they are not mentioned in this leaflet, please tell your doctor or pharmacist.

### 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:

Bulgarian Drug Agency

8 Damyan Gruev Str.,

Sofia 1303, tel.: 02 8903417,

website: [www.bda.bg](http://www.bda.bg)

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

### 5. How to store Spasmobloc

Keep out of reach of children

To be stored below 25 °C

Keep your tablets in the original container to protect from light and moisture.

Do not use this medicine after the expiry date printed on the blister and carton. The expiry date refers to the last day of that month.

Do not dispose of medications in wastewater or household waste. Ask your pharmacist how to discard medications you no longer use. These measures will help to protect the environment.

### 6. Contents of the pack and other information

What Spasmobloc contains

- The active substances per tablet are: Metamizole sodium 500 mg, Pitofenone hydrochloride 5 mg, Fenpiverinium bromide 0,1 mg.

- The other ingredients (excipients) are: wheat starch, lactose monohydrate, gelatin, microcrystalline cellulose, talc, sodium hydrogen carbonate, magnesium stearate.

#### What Spasmobloc looks like and contents of the pack

Description

Spasmobloc is white or almost-white, round, flat tablets with a break line on one side. The tablet can be divided into two equal halves.

Package

10 tablets in blister PVC / Al

2 blisters with leaflet in carton box.

#### Marketing Authorisation Holder and Manufacturer

Adipharm EAD

Blvd. Simeonovsko shosse № 130

1700 Sofia, Bulgaria

#### Date of last revision of the leaflet

November 2017