PACKAGE LEAFLET: INFORMATION FOR THE USER

SPAZMOL

10mg + 500mg film-coated tablets

BUTYLSCOPOLAMINE, PARACETAMOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. WHAT SPAZMOL IS AND WHAT IS IT USED FOR

SPAZMOL tablets are a combination of two active substances: butylscopolamine and paracetamol.
Butylscopolamine belongs to the group of medicines for the treatment of functional disorders of the digestive system, called belladonna alkaloids, semisynthetic, quaternary ammonium compounds, and paracetamol, the other active ingredient of the combination, is used to relieve pain and lower fever, and it belongs to the group of medicines called analgesics and antipyretics.
SPAZMOL film coated tablets contain combination of butylscopolamine and paracetamol that is indicated for the treatment of painful conditions caused by spasms in the gastrointestinal tract (stomach, intestine, bile) and in the genito-urinary system (painful menstruation).

2. BEFORE YOU TAKE SPAZMOL

Do not take SPAZMOL

- If you are allergic to Butylscopolamine, Paracetamol, or any of the other ingredients of this medicine
- If you have narrow-angle glaucoma (decreased vision, redness and eye pain)
- if you have enlarged prostate

- if you have mechanical narrowing of the digestive tract or very extensive section of the colon (megacolon)
- if you have myasthenia gravis (muscle weakness)
- If you have severely impaired liver function
- If you have rapid or irregular heartbeat or
- If you have porphyria (a metabolic disorder)

Take special care with SPAZMOL, so you must tell the doctor

- if you are already taking paracetamol or butylscopolamine
- if after 3-4 days the pain did not stop
- if you notice signs of allergy (rash or itchy skin, shortness of breath, cough)
- if you have a rapid or irregular heartbeat
- if you have impaired liver or kidney function
- if you have Gilbert's disease (jaundice, nausea, fatigue, diarrhea, headache, loss of appetite resulting due to disturbances in the metabolism of bilirubin)
- if you have a G6PD (Glucose-6-phosphate dehydrogenase) deficiency (a hereditary disease affecting red-blood cells), since elevated doses of acetylsalicylic acid could lead to hemolysis (destruction of red blood cells)

Children under 12 are not recommended to use this fixed combination due to insufficient evidence on safety!
If you experience pain and redness in the eye followed by impaired vision or loss of vision, contact your doctor or ophthalmologist!

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
For the purpose of prescribing the right dose of SPAZMOL film tablets, it is especially important that your doctor knows if you are taking -

- Other medicines for pain relief,
- Amantadine - a medicine to treat Parkinson's disease and influenza,
- Anticholinergics (ipratropium, oxitropium, tiotropium),
- Medicines to treat depression (imipramine, amitriptyline),
- Medicines to treat disorders of heart rhythm (quinidine, disopyramide)
- Medicines to treat allergies (antihistamines)
- Medicines to stimulate the motility of the gastrointestinal tract (metoclopramide)
- Beta-sympathomimetics (isoprenaline, dobutamine)
- Medicines for the treatment of gout (probenecid).

It is necessary to avoid concomitant use of SPAZMOL tablets and alcohol!

Children and adolescents

Children under 12 are not recommended to use this fixed combination due to insufficient evidence on safety!

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Safety of SPAZMOL during pregnancy has not been fully investigated and therefore it can be used only if the expected benefit to the mother outweighs the potential risk to the fetus.
SPAZMOL is excreted into the breast milk. Breast-feeding should be discontinued during treatment.

Driving and using machines

SPAZMOL should not affect your ability to drive and use machines.

3. HOW TO TAKE SPAZMOL

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage
For oral use only. Take tablet(s) with plenty of liquid in order to decrease the chance of indigestion.
Your doctor will decide on the appropriate dose, depending on your condition and whether you are taking other medicines.
The usual single dose for persons over 12 years of age is one to two tablets, while the maximum daily dose is 6 tablets (60 mg + 3000).
The maximum daily dose should not be exceeded.
The time interval between doses, unless required otherwise, should be at least 8 hours.

Patients with severe hepatic impairment
This group of patients should not take SPAZMOL.

Patients with renal impairment
Your doctor will adjust the dose depending on the degree of renal impairment.

If you think SPAZMOL tablets have too weak or too strong effect on your body, you should contact your doctor.

If you take more SPAZMOL than you should
In case of overdose contact your doctor immediately so that you can be provided with immediate medical help. The most common symptoms are nausea, vomiting, sweating, drowsiness, weakness, vision disorder, increased heart rate, dry mouth and skin redness.

Talk to your doctor or pharmacist if you have any additional questions.

If you forget to take SPAZMOL
If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.
Do not take a double dose to make up for a forgotten dose.

If you stop taking SPAZMOL
If you end treatment with **SPAZMOL** early, or if you interrupt treatment, then it is expected that the desired therapeutic effect will not set in, or that your condition will get worse again.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SPAZMOL can cause side effects, although not everybody gets them.
Side effects have occurred with the use of SPAZMOL tablets:

Less frequently (in more than 1 in 1,000 patients, but less than 1 in 100 patients) may occur anaphylactic reactions with episodes of shortness of breath and anaphylactic shock, rapid heartbeat, dry mouth, **rarely** (in more than 1 in 10,000 patients, but less than 1 in 1000 patients), may occur skin reactions, urinary retention, and **very rarely** (in less than 1 in 10,000 patients) hypersensitivity reactions including swelling of the larynx, hives, spasm of the airways, low blood pressure and collapse, reduced number of platelets and white blood cells.

Immediately stop taking SPAZMOL tablets and contact your doctor if any of the following occurs:

- If you experience swelling of the face, lips, tongue and / or throat which may cause difficulty in breathing or swallowing
- If you experience swelling of the hands, feet or ankles
- If you get a rash.

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

5. HOW TO STORE SPAZMOL

Keep out of the reach and sight of children.

Do not store above 25 ºC.

Do not use **SPAZMOL** after the expiry date which is stated on the label, 2 years from the date of manufacture.

6. FURTHER INFORMATION

What SPAZMOL contains

Each tablet contains 10 mg of butylscopolamine and 500 mg of paracetamol as active substances.
Other ingredients: microcrystalline cellulose, povidone, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate
FILM: Opadry II white, purified water

What SPAZMOL looks like and contents of the pack

20 (2x10) tablets of 10 mg of butylscopolamine + 500 mg of paracetamol in a blister pack, in a box.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

ZADA Pharmaceuticals d.o.o. Donji Bistarac bb, 75300 Lukavac, Bosna i Hercegovina.

Manufacturer of the medicinal product

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