**Package leaflet: Information for patient**

ZADA PHARMACEUTICALS

**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.

**SPAZMOL film-coated tablets 10+500 mg**
*Butylscopolamine + paracetamol*

**What is in this leaflet**


**1. What SPAZMOL is and what it is used for**
**SPAZMOL** are film-coated tablets. **SPAZMOL** is a combination of two active substances: butylscopolamine and paracetamol. Butylskopolamine belongs to a group of medicines for the treatment of functional disorders of the digestive system, called beladone alkaloids, semisynthetic, quaternary ammonium compounds, and paracetamol, another active substance of this combination, is used to relieve pain and reduce fever, and belongs to a group of medicines called analgesics and antiretics.
Your doctor has prescribed **SPAZMOL** for the treatment of painful conditions caused by gastrointestinal cramps (stomach, intestines, bile) and genito-urinary system (painful periods).

**2. What you need to know before you take SPAZMOL**
**Do not take SPAZMOL:**
- if you are allergic to any of its ingredients (See What is **SPAZMOL**?),
- if you have untreated elevated eye pressure narrow-angle glaucoma (initially no symptoms, and then decreased vision, redness and pain in the eye),
- if you have an enlarged prostate without being able to completely empty your bladder,
- if the cutter has told you that you have mechanical constrictions in the digestive tract or a very large part of the colon (megacolon),
- if you have myasthenia gravis (a disease manifested by muscle weakness),
- if you have severe damage to your liver function,
- if you have rapid or irregular heartbeat or
- Porphyria (a disorder of metabolism manifested by abdominal pain, nausea, vomiting, skin hypersensitivity to light).
If you are not sure whether you should start taking **SPAZMOL**, contact your doctor.
What are the appropriate precautions for use?
Inform your doctor about any health problems you have or have had, as well as any allergies.
Tell your doctor if:
- you are already taking paracetamol or butylscopolamine;
- after 3-4 days the pains have not stopped, in which case the doctor will re-examine you and refer you for more detailed examinations;
- signs of allergy occur (skin rash or itching, shortness of breath, cough);
- have a rapid or irregular heartbeat;
- you have impaired liver or kidney function;
- you have Gilbert's syndrome (jaundice, nausea, fatigue, diarrhea, headache, decreased appetite due to disorders in bilirubin metabolism);
- you know that your family or you have a deficiency in glucose-6-phosphate dehydrogenase, an enzyme that participates in sugar metabolism;
- you have high eye pressure.
Children under 12 years of age are not recommended to use this fixed combination because of a lack of evidence of safety in use!
If you experience pain and redness of the eyes with impaired vision or loss of vision, contact your doctor or ophthalmologist immediately!

**Taking SPAZMOL with other medicines**
Basically, SPAZMOL can be taken with other medicines. However, it is important that you tell your doctor about other medicines you are taking, including those that are prescribed over the counter, as some medicines may affect the action of others.
When prescribing the right dose of **SPAZMOL**, it is especially important that your doctor knows if you are taking it
- other painkillers,
- amantadine - a medicine for the treatment of Parkinson's disease and influenza,
- anticholinergics (ipratropium, oxytropium, tiotropium),
- medicines for the treatment of depression (imipramine, amitriptyline),
- medicines for the treatment of heart rhythm disorders (quinidine, disopyramide),
- medicines for the treatment of allergies (antihistamines),
- medicines to promote digestive tract motility (metoclopramide),
- beta-sympathomimetics (isoprenaline, dobutamine),
- medicines for the treatment of gout (probenecid).
Concomitant use of **SPAZMOL** and alcohol should be avoided!

**Children and adolescents**
Children under 12 years of age are not recommended to use this fixed combination because of a lack of evidence of safety in use!

**Pregnancy**
The use of **SPAZMOL** is not recommended in pregnancy. The medicine can only be used if your doctor estimates that the potential benefit to you (the mother) outweighs the potential risk to the fetus.

**Breast-feeding**
The use of the drug during lactation should be avoided.
Impact on vehicle management and machine operation
There are no data on the adverse effects of **SPAZMOL**, administered at the recommended doses, on the ability to drive or operate machinery.
It is best to take **SPAZMOL** with enough fluid to reduce the risk of indigestion. Swallow the film pills whole without breaking or chewing.
Take **SPAZMOL** to the extent and in the manner prescribed by your doctor.
Your doctor will decide on the right dose of **SPAZMOL**, depending on your condition and whether you are taking other medicines.
The usual single dose for people over 12 years of age

is 1-2 tablets, while the maximum daily dose is 6 tablets (60 + 3000 mg).
The maximum daily dose should not be exceeded. Unless otherwise indicated, the interval between doses 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 your dose depending on the degree of damage to your kidney function.

**If you take more SPAZMOL than you should**
In the event of an overdose, contact your doctor immediately so that you can receive immediate medical attention. The most likely symptoms will be nausea, vomiting, sweating, drowsiness, malaise, impaired vision, increased heart rate, dry mouth and redness of the skin.

**If you forget to take SPAZMOL**
You should take **SPAZMOL** as prescribed by your doctor. However, if you forget to take a single dose, do not take the extra dose. Just continue with your usual schedule of taking the medicine.

**4. Possible side effects**
Any medication can have side effects. **SPAZMOL** is generally well tolerated. You may never have the side effects listed in the text of the leaflet. If they do occur, tell your doctor or pharmacist about any of these or other unusual symptoms.
During the administration of **SPAZMOL**, skin reactions, anaphylactic reactions with episodes of shortness of breath and anaphylactic shock, rapid heartbeat, dry mouth, urinary arrest, hypersensitivity reactions including larynx swelling, urticaria, respiratory spasm, blood pressure drop and collapse may occur. reduced blood platelets and white blood cells.
Contact your doctor or pharmacist for more information on side effects.
Stop taking **SPAZMOL** immediately and contact your doctor in any of the following cases:
- if your face, lips, tongue and / or throat begin to swell, which may cause difficulty in breathing or swallowing
- if you feel the swelling of your hands, feet or ankles
- if you get a rash.

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

**5. How to store SPAZMOL**
Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

**6. Contents of the pack and other information**
**What SPAZMOL contains**
**SPAZMOL** 10 + 500 mg
Each tablet contains 10 mg of butylscopolamine and 500 mg of paracetamol as active substances.
Excipients: microcrystalline cellulose, povidone, croscarmellose sodium, colloidal silica, magnesium stearate.
Film: Opadry II white, purified water

**What SPAZMOL looks like and contents of the pack**
Box of 20 tablets of 10 mg butylscopolamine + 500 mg paracetamol in blister pack (2 blisters x 10 tablets)

**Marketing Authorisation Holder and Manufacturer**
ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75300 Lukavac
Bosnia and Herzegovina

**Date and number of renewal of marketing authorization**
**SPAZMOL**, film-coated tablets:
**Number:** 04-07.3-2-6613/16 **Date:** 15.11.2016.

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