PACKAGE LEAFLET: INFORMATION FOR THE USER

SPAZMOL PLUS 10 mg/500 mg Film Coated Tablets
Taken by mouth

Active Substance: Each film-coated tablet contains 10 mg hyoscine-N-butylbromide and 500 mg paracetamol.
Excipients: Polyvinylpyrrolidone K25, microcrystalline cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate.
Film coating agents (Opadry 03-B-22320 Yellow): Hydroxypropylmethylcellulose (E 464), titanium dioxide (E 171), polyethylene glycol, tartrazine (E 102), indigo carmine (E 132).

Read all of this PACKAGE 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. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either **higher** or **lower** dose other than recommended to you.*

In this leaflet:

1. WHAT SPAZMOL PLUS IS AND WHAT IT IS USED FOR

SPAZMOL PLUS belongs to a group of medicines known as combination of antispasmodics and painkillers.

Each film-coated tablet contains 10 mg hyoscine-N-butylbromide and 500 mg paracetamol as active substances.
The product is presented in blister packs of 20 film-coated tablets. The film-coated tablets are yellow, slightly convex, odorless and round.

SPAZMOL PLUS is used to relieve pain and cramps (spasm) occurring as sudden, severe seizures in the following organ muscles:
- Stomach
- Intestines
- Bladder and urinary tract
- Biliary tract

SPAZMOL PLUS is used to relieve pain due to functional problems in female genital organs (e.g., menstrual pain).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPAZMOL PLUS

DO NOT TAKE SPAZMOL PLUS, if

- You are allergic (hypersensitive) to the active substances hyoscine-N-butylbromide and paracetamol or to any of the other ingredients of SPAZMOL PLUS,
- You have untreated glaucoma, an eye disease causing extremely increased intraocular pressure,
- You have a disease that leads to accumulation of urine in your bladder and difficulty passing urine (e.g. growth of prostate gland in men),
- You have intestinal obstruction due to mechanical obstruction in your digestive system or paralysis of your bowel movements,
- You have a disease that causes your heart to beat too fast,
- You have a disease called megacolon which causes partial enlargement of the colon and is manifested by persistence constipation and abdominal growth,
- You have a rare disease called myasthenia gravis which leads to severe muscles weakness,
- You are pregnant,
- You are breast-feeding,
- You are under 10 years of age.

TAKE SPECIAL CARE with SPAZMOL PLUS, if

- You have Gilbert's syndrome (a familial congenital disease characterized by fatigue, nausea, upper abdominal pain and jaundice),
- You have anemia,
- You have lung disease,
- You have liver dysfunction,
- You have kidney dysfunction,
- You have an eye disorder called narrow-angle glaucoma,
- You have an obstruction in your intestine or urinary tract,
- You have a heart rhythm disorder with an excessive increase in your heart rate,
- You have a problem with your thyroid gland that lead to excessive thyroid hormone secretion,
- You have constipation,
- You have an increased body temperature.

Redness and rash on the skin, or another skin reaction may occur in the first or subsequent doses of paracetamol in first-time users or those who have used it before. In that case, discontinuation of the drug administration and institution of an alternative treatment is needed under doctor advice. Anyone who has experienced a skin reaction with paracetamol should not use the drug or any other paracetamol-containing products again. This situation may cause serious and fatal skin reactions, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). For a description of these diseases, see section "4. POSSIBLE SIDE EFFECTS ".

Please consult your doctor if these warnings were applicable to you even at any time in the past.

Using SPAZMOL PLUS with food and drink
There is no evidence regarding the interaction of SPAZMOL PLUS with food and drinks. SPAZMOL PLUS can be taken with or without food.

Pregnancy
Consult your doctor or pharmacist before using this medicine.
Please inform your doctor if you think that you are pregnant (or may become pregnant). SPAZMOL PLUS should not be used during pregnancy.

If you realize that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist before using this medicine.
If you are breast-feeding, you should not use SPAZMOL PLUS.

Driving and using machines
Some people may develop a disorder in the adaptation of the eyes to near and far vision during the use of SPAZMOL PLUS. If you experience problems with your vision, do not drive or use machines until your visual problems have resolved. Please consult your doctor before driving or using machines.

Important information about some of the ingredients of SPAZMOL PLUS
This medicinal product contains tartrazine. It may cause allergic reactions.

Using with other medicines
If you are using the following medicines, you must inform your doctor because of risk of interaction with SPAZMOL PLUS:

Possible interaction of active substance hyoscine-N-butylbromide
When SPAZMOL is used with the following medicines, anticholinergic effects such as dry mouth, constipation, blurred vision, sweating, accumulation of the urine in the bladder, increased heart rate may be intensified:
- Tricyclic antidepressant medicines used to treat psychological breakdown (depression)
- Antihistaminic medicines which are effective for allergic diseases or motion sickness
- Quinidine and disopyramide used to control heartbeat
- Amantadine, a medicine used for Parkinson disease
- Other anticholinergic medicines used for disease causing shortness of breath such as asthma (e.g. tiotropium, ipratropium)
- Medicines such as haloperidol, fluphenazine that are used to treat mental disorders as adjuvant.

- Metoclopramide: A dopamine antagonist used to prevent vomiting. When used together with SPAZMOL PLUS, the effects of both medicines on gastrointestinal tract may decrease.
- Beta-adrenergic agents: Concomitant use of SPAZMOL PLUS with beta-adrenergic agents, which are used to treat high blood pressure, to prevent chest pain (angina) and to treat irregular heartbeat and heart attack, may increase your heart rate.

Possible interaction of active substance paracetamol
When used SPAZMOL PLUS with the following medicines and alcohol, it may cause liver damage.
- Certain sleeping medicines and medicines that used to treat epilepsy (e.g. glutethimide, phenobarbital, phenytoin, carbamazepine)
- Rifampicin, an antibiotic used to treat tuberculosis

- Propantheline: Where gastric emptying is slowed down, as for instance with an antispasmodic medicine propantheline (used to treat irritable bowel syndrome and involuntary urination), the onset of the effect of SPAZMOL PLUS is delayed as a result of the decrease in the absorption rate of paracetamol.
- Chloramphenicol: When chloramphenicol, an antibiotic used in the treatment of serious infections, is used together with SPAZMOL PLUS, the risk of toxicity increases as the half-life of chloramphenicol may be increased.
- Your doctor will monitor you closely while you are using warfarin that is a blood-thinning medicine
- AZT (zidovudine): Concomitant use of SPAZMOL PLUS and AZT (zidovudine), which is a medicine used to slow the progression of AIDS, may cause a decrease in the number of white blood cells (leukocytes) due to the interaction of AZT (zidovudine) with the paracetamol content of the medicine. Therefore, SPAZMOL PLUS should only be taken together with AZT following medical advice.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO USE SPAZMOL PLUS

Instructions for proper use and dose/frequency of administration

Always use SPAZMOL PLUS exactly as your doctor has told you.
1-2 tablets of SPAZMOL PLUS is administered 3 times daily in adults.
SPAZMOL PLUS film-coated tablet may be used in children over 10 years of age, if necessary.
The total daily dose should not exceed 6 tablets.

SPAZMOL PLUS should not be used over a prolonged period of time or in higher doses without a prescription from the doctor.

Route and method of administration
SPAZMOL PLUS is taken only by mouth.
Please take tablets whole with adequate water (e.g. a glass of water) without chewing.

Different age groups
Use in children
The use of SPAZMOL PLUS in children under 10 years of age is not recommended.

Use in the elderly
No dose adjustment is necessary in the elderly.

Use in special conditions

Liver / Kidney failure
Because it contains the active substance paracetamol, patients with severe kidney or liver dysfunction should be closely monitored by a doctor.

If you have the impression that the effect of SPAZMOL PLUS is too strong or weak, talk to your doctor or pharmacist.

If you use more SPAZMOL PLUS than you should
If you have used more SPAZMOL PLUS than you should, talk to your doctor or pharmacist.

Overdose may cause dry mouth, accumulation of urine in the bladder, reddening of the skin, reduction of gastrointestinal activity, transient visual disturbances, decreased blood pressure and respiratory problems.

If you forget to use SPAZMOL PLUS
It is important that you take your dose as described to you by your doctor. If you forget to take your medicine, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose, take your normal dose, and continue the treatment.

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

Effects that may occur if you stop using SPAZMOL PLUS
None.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in people with sensitivity to ingredients of SPAZMOL PLUS.

Stop taking SPAZMOL PLUS, tell your doctor or go to the nearest hospital emergency department IMMEDIATELY if you experience any of the following side effects:
Anaphylactic reactions (sudden, severe allergic reactions) and anaphylactic shock (with feeling faint) may occur. Red itchy rash may spread all over whole body. Swelling in the whole body or around the eyes may occur. Difficulty in breathing and swallowing may occur due to narrowing of the airway. You may lose consciousness due to possible circulatory disorders. This situation may result in death. The frequency of these situations is unknown.

These are all very serious side effects.
If you have any of these, it means that you have serious allergy to SPAZMOL PLUS. You may need urgent medical attention or hospitalization.
All of these very serious side effects are very rare.

Frequency of reported side effects is as follows:

Uncommon (may affect less than 1 in 100 patients but more than 1 in 1,000 patients):
- Dyshidrosis (a skin disease appears especially with abnormal sweating of the hands and feet)
- Skin reactions, nausea
- Dry mouth

Rare (may affect less than 1 in 1,000 patients but more than 1 in 10,000 patients):
- Decreased blood pressure
- Increased heart rate
- Skin rash, itching, urticaria, allergic edema (swelling due to fluid accumulation in the tissues) and angioedema (swelling due to fluid accumulation in the face and throat), acute generalized exanthematous pustulosis, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis (including fatal results)

Acute generalized exanthematous pustulosis: In large parts of the body, sudden reddening of the skin and pinhead-sized pus-filled blisters occur. Usually accompanied by fever.
Erythema multiforme: Symmetrical, reddened and blistering rash occurs usually on the arms and legs. The rashes are patch-like and have a center point.
Stevens-Johnson syndrome: Usually begins with fever, sore throat and fatigue. Then redness of the skin, painful rash and fluid-filled blisters occur. There are painful wounds in the mouth and genital organs.
Toxic epidermal necrolysis: It is a severe form of Stevens-Johnson syndrome. In the whole body, the upper layer of the skin is separated from the lower layer of the skin.

These are all rare, mostly caused by medicines, severe skin diseases.

Side effects with unknown frequency (the frequency cannot be calculated from the available information) are listed below:
- Reduction in the number of all blood cells, reduction in the number of blood platelets and white blood cells (may occur relating to the active substance paracetamol).
- Sudden, severe allergic reactions and feeling faint or dizzy (shock) may occur.
- Bronchial spasms (especially in people with a history of asthma or allergies)
- Increase in some liver enzymes (transaminases)
- Urine accumulation in the bladder and difficulty passing urine

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SPAZMOL PLUS

Keep SPAZMOL PLUS out of the reach and sight of children, and in its original package.
Store at room temperature below 25°C.

Use it in line with the expiry date.
Do not use SPAZMOL PLUS after the expiry date, which is stated on the package.

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.

Marketing Authorization Holder:
Deva Holding A.Ş.
Küçükçekmece - İSTANBUL/TÜRKİYE

Manufacturing Site:
Deva Holding A.Ş.
Kapaklı - TEKİRDAĞ/TÜRKİYE

This package leaflet was approved on 21/11/2017.