

PACKAGE LEAFLET: Information for the patient

SPAZMOFARMA

Tablets – 5 mg

(Oxyphenonium bromide)

Read all of this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

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

1. WHAT SPAZMOFARMA IS AND WHAT IT IS USED FOR

Spazmofarma contains oxyphenonium bromide, which is a substance that affects impulse transmission from vagus nerve endings to smooth muscle; it relaxes spasms due to vagus nerve stimulation and reduces excess gastric secretion. Oxyphenonium bromide is slowly absorbed after oral use of tablets of this substance. This medicine is partially absorbed by the gastrointestinal tract; average absorption rate of a single oral dose is 5 - 6%. The active substance in the circulating blood is mainly present in the plasma fraction.

Spazmofarma is indicated in the treatment of spasms of smooth muscles in the gastrointestinal tract, bile duct, urethra and genital tract.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPAZMOFARMA

Do not take Spazmofarma if:

- you are allergic to oxyphenonium bromide or to any of the excipients of this medicine;
- you have glaucoma;
- you have obstructive uropathy (e.g., obstruction of bladder neck due to prostatic enlargement);
- you have obstructive disease of the gastrointestinal tract;
- you have tachycardia or tachycardiac arrhythmia;
- you have toxic megacolon complicated by ulcerative colitis;
- you have myasthenia gravis.

If you think you have any of the above mentioned conditions, do not take the tablets, first talk to your doctor and follow the given advice. If you go to another doctor / dentist, inform them that you are taking Spazmofarma.

Warnings and precautions

Talk to your doctor before taking Spazmofarma if:

- you are allergic to other medicines, particularly to those in the same group as Spazmofarma;
- you are taking other medicines such as antidepressants, antihistamines or anticholinergics, because these medicines might increase the possibility of side effects of Spazmofarma;
- you are pregnant or planning to get pregnant;
- you are debilitated with chronic pulmonary disease, because reduced bronchial secretions could lead to bronchial mucus plugs formation;
- you are older than 40 years of age because of higher incidence of glaucoma in this age group.

One of the early signs of partial intestinal obstruction, particularly in patients with ileostomy or colostomy, is diarrhea. In such cases, the treatment should be considered inappropriate and possibly harmful.

In patients who are being treated for gastric ulcer, this medicine may delay stomach emptying, thus possibly interfering with the treatment of gastric ulcer.

Other medicines and Spazmofarma

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines without prescription. Inform your doctor if you are taking the following medicines:

- antidepressants, antihistamines or anticholinergics. Concomitant use of any of these drugs with Spazmofarma may increase the possibility of experiencing side effects or they may affect the way Spazmofarma acts. You may need to change the dose or take other drugs. Your doctor or pharmacist will advise you.

Taking Spazmofarma with food and drinks

Take Spazmofarma following your doctor's advice.

Pregnancy and breastfeeding

If you are pregnant or think you may be pregnant or are planning a pregnancy, ask your doctor or pharmacist for advice before taking this medicine. Treatment with Spazmofarma should be avoided during pregnancy.

If you are breastfeeding ask your doctor or pharmacist for advice before taking this medicine. Oxyphenonium bromide is excreted in breast milk and is harmful for the child's health. Thus, its use in breastfeeding mothers is not recommended.

Driving and using machines

Patients using Spazmofarma should be warned not to drive or operate machinery, because it may cause drowsiness and blurred vision.

Important information about some of the excipients of Spazmofarma

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE SPAZMOFARMA

Always take this medicine exactly as your doctor or pharmacist has told you. Take tablets with a glass of water, at the same hour of the day, every day.

Adults: 5 - 10 mg (1 – 2 tablets) up to 4 times a day, for several days. Then, dosage may be decreased depending on patient's response to treatment.

Children of school age: 2.5 mg (1/2 tablet), 1-3 times a day.

Your doctor may prescribe a different dose depending on your condition and reaction to the medicine. Your doctor may prescribe Spazmofarma for a longer time period. Ask your doctor if you are not sure for the duration of treatment.

If you take more Spazmofarma than you should

If you take more Spazmofarma tablets than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on the actions that should be taken.

If you forget to take Spazmofarma

If you forget to take one or more doses, take the next dose at the next prescribed time.

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Sometimes they may be serious and sometimes not. Do not be alarmed by this list of possible side effects! You may not experience any of them.

Talk to your doctor if you have any of the following side effects:

- tachycardia (cardiovascular system);
- blurred vision, drowsiness, headache (central nervous system);
- constipation (gastrointestinal tract);

- urine retention and other urinary disorders (genitourinary system);
- dryness of mouth, dryness of throat, increased intraocular pressure (glaucoma), reduced sweating.

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE SPAZMOFARMA

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

Do not use Spazmofarma after the expiry date which is stated on the package.

Store below 25°C.

Keep in the original packaging to protect it from light and humidity!

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Spazmofarma contains

The **active substance** is Oxyphenonium bromide.

Each tablet contains 5 mg oxyphenonium bromide.

The **excipients** are: maize starch, lactose monohydrate, povidone, purified talc, magnesium stearate.

Contents of the pack

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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