PACKAGE LEAFLET: Information for the patient

SULFAMETOPRIM

Tablets – (400 mg / 80 mg)

(Sulfamethoxazole / Trimethoprim)

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

In this leaflet:

1. WHAT SULFAMETOPRIM IS AND WHAT IT IS USED FOR

Sulfametoprim contains the active substances sulfamethoxazole and trimethoprim.

Sulfamethoxazole (SMZ) inhibits the bacterial synthesis of dihydrofolic acid, by competing with *p*-aminobenzoic acid.

Trimethoprim (TMP) inhibits the production of tetrahydrofolic acid, by inhibiting the dihydrofolate reductase enzyme. This combination blocks two consecutive phases of the bacterial biosynthesis of essential nucleic acids and proteins and usually exerts a bactericidal action.

Sulfametoprim tablet is indicated in:

- respiratory tract infections such as: pneumonia by *Pneumocystis carinii*, acute exacerbation of chronic bronchitis, bronchiectasis, lung abscess, bronchopneumonia, sinusitis and otitis media;
- genitourinary tract infections such as: urethritis, acute and chronic cystitis, pyelitis, pyelonephritis, prostatitis, gonorrhea;
- gastrointestinal tract infections, caused by *Salmonella typhi* and *paratyphi* etc., such as dysentery, traveler's diarrhea, typhoid and paratyphoid fever, cholera;
- toxoplasmosis and nocardiosis.

Except pneumonia by *Pneumocystis carinii* where it is a first-line treatment, toxoplasmosis and nocardiosis, in the other indications such as in the exacerbations of chronic bronchitis, urinary tract infections and in otitis media in children, the use of Sulfametoprim should be carefully considered, only when there is a bacteriological evidence for sensibility to this drug and a strong reason to use it and not a single antibacterial.

2. BEFORE YOU TAKE SULFAMETOPRIM

Do not take Sulfametoprim if:

- you are hypersensitive to sulfonamides and trimethoprim or to any of the excipients of the tablet;
- you have severe impairment of liver parenchima;
- you have blood dyscrasia or porphyria;
- you have glucose-6-phosphate dehydrogenase deficiency;
- you suffer of severe kidney failure;
- you are during pregnancy.

Sulfametoprim should not be used in children born prematurely and in newborns (in the first 6 weeks of life).

Sulfametoprim administration should be discontinued when rash or blood disorders appear.

Take special care with Sulfametoprim

During long - term treatment, analysis of peripheral blood should be made, while for patients with renal function impairment, urine analyses and kidney function tests should be made.

Treatment should be accompanied by large amounts of fluids, in order to prevent crystalluria and the formation of stones.

Ask your doctor before you take Sulfametoprim if:

- it will be used in patients with renal, liver or thyroid function impairment;
- it will be used in allergic patients and those with bronchial asthma;
- it will be used in patients susceptible to folate deficiency (the elderly patients and when high doses of Sulfametoprim are used for a long time);
- it will be used in predisposed patients for hyperkalemia;
- you are breastfeeding;
- you have an infection caued by β-hemolytic streptococcus of group A.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Sulfametoprim. Please contact with your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Sulfametoprim if you have been given any other drug during treatment.

- The action of sulfonamides may be antagonised from *p*-aminobenzoic acid and the compounds derived from it, mainly from potassium aminobenzoate and the procaine group of the local anaesthetics.
- Sulfamethoxazole can displace the antidiabetics of the group of sulfonylureas, phenytoin, oral anticoagulants and methotrexate from their binding with the plasmatic proteins. At the same time, sulfamethoxazole reduces the metabolism of these drugs.
- The combination of Sulfametoprim with drugs that inhibit hematopoiesis, increases the risk of developing leucopenia, thrombocytopenia or megaloblastic anemia. Such drugs are: azathioprine, azidothymidine, carbamazepine, chloramphenicol, clozapine, gancyclovir, phenothiazines, procainamide and antitumorals.
- Trimethoprim may increase plasmatic concentrations of digoxin, as a result of the reduction of tubular secretion.
- Sulfonamides reduce plasmatic concentrations of cyclosporin when used concomitantly.
- Methenamine should not be used concomitantly with Sulfametoprim as it increases the risk for crystalluria.

- Sulfonamides cause photosensibility, thus they can enhance the photosensibilisant effect of griseofulvine, phenothiazines, sulfonylurea, tetracyclines, thiazide diuretics, analogues of vitamin A.
- Sulfonamides displace sulfinpyrazonine from its binding with plasmatic proteins by increasing its toxicity.
- Trimethoprim, either alone or combined with sulfamethoxazole, should not be combined with dofetilide, since the plasmatic concentration of the last one markedly increases.
- The risk for lactic acidosis by metformin markedly increases when it is combined with Sulfametoprim.
- Simultaneous administration of Sulfametoprim with pyrimethamine and methotrexate may increase the risk for pancytopenia and megaloblastic anemia.
- Sulfametoprim reduces renal excretion of zidovudine, zalcitabine and lamivudine.
- Trimethoprim and dapsone increase the plasmatic concentrations of each other.
- Rifampicine reduces the concentration of trimethoprim.
- ACE-inhibitors may cause severe hyperkalemia when taken simultaneously with Sulfametoprim in patients with renal disorders.
- In older patients, who have concomitantly received this antibacterial with diuretics (mainly thiazides), it is observed an increase of the incidence for thrombocytopenia with purpura.

Pregnancy

Category C.

Inform your doctor or pharmacist if you are pregnant or you are planning to become pregnant.

Do not use Sulfametoprim in the period of pregnancy.

Breastfeeding

Inform your doctor or pharmacist if you are breastfeeding. Care should be taken during breastfeeding because sulfamethoxazole, as well as trimethoprim, are excreted with breast milk, thus breastfeeding is discontinued.

The use of Sulfametoprim during breastfeeding should be avoided.

Driving and using machinery

Side effects that harm the ability to drive and use machinery may occur.

3. HOW TO TAKE SULFAMETOPRIM

Always take Sulfametoprim as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Sulfametoprim are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least half glass of water.

Dosage is as follows:

Adults:

In severe infections are used 960 mg (2 tablets), every 12 hours and which may increase to 1.44 g (3 tablets), every 12 hours; if the treatment lasts more than 14 days, there are used 480 mg, every 12 hours.

Acute otitis media is treated for 10 days.

Acute riacutizations of chronic bronchitis in adults are treated for 10 - 14 days.

Infections of the lower urinary tract are treated for 3 - 5 days.

Infections of the upper urinary tract are treated for 14 days; shigellosis is treated for 5 - 7 days.

In gonorrhea are given 1.92 g (4 tablets), every 12 hours, for 2 days.

In the treatment of infections from *Pneumocystis carinii* may be given 120 mg / kg of body weight daily, in divided doses, for 14 days.

In traveller´s diarrhea are used 960 mg, every 12 hours, for 5 days.

Children

240 mg every 12 hours in children with age from 2 - 5 years old.

480 mg every 12 hours in children with age from 6 - 12 years old.

Patients with impaired renal function

Sulfametoprim dose should be reduced in patients with impaired renal function.

If you have taken more Sulfametoprim

If you have taken more Sulfametoprim than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Sulfametoprim

If you forget a dose (or more doses), take the next dose when it is time to take it usually.
Do not take a double dose (or higher) to make up for a forgotten dose (doses).
If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Sulfametoprim may cause side effects, although not everybody manifests them. Sulfametoprim is well tolerated in the recommended doses. Inform your doctor for the following side effects that may appear to you:

- gastrointestinal disturbances (nausea, vomiting, glossitis, pancreatitis, stomatitis, diarrhea and in rare cases membranous enterocolitis);
- allergic skin reactions (urticaria, erythema multiforme, Stevens-Johnson syndrome, itching, serum disease and photosensibilisation);
- hypersensitivity reactions;
- hematological disorders, such as: agranulocytosis, aplastic anemia, megaloblastic anemia, thrombocytopenia, hypothrombinemia, methemoglobinemia;
- central nervous system reactions: headache, peripheral neuritis, convulsions, ataxia, dizziness, hallucinations, apathy.

If any of the above mentioned side effects appears, the treatment with Sulfametoprim should be discontinued.

Other side effects classified in terms of frequency.

Very common (may affect more than 1 in 10 people):

- increased amount of potassium in the blood.

Common (may affect up to 1 in 10 people)

- an infection called thrush or candidiasis which can affect your mouth or vagina.

Very rare (may affect up to 1 in 10,000 people)

- fever (high temperature) or frequent infections
- inflammation of the eye which causes pain and redness
- low levels of sodium in your blood
- heart problems
- jaundice (the skin and the whites of your eyes turn yellow); this can occur at the same time as unexpected bleeding or bruising
- arthritis
- problems with your urine; difficulty passing urine; passing more or less urine than usual; blood or cloudiness in your urine
- kidney problems
- ringing or other unusual sounds in your ears
- depression
- muscle pain and/or muscle weakness in HIV patients
- loss of appetite
- cough

Not known (frequency cannot be estimated from the available data)

- Psychotic disorder (a mental state in which you may lose touch with reality)

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE SULFAMETOPRIM

Keep away from children.

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

Store below 25°C.

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

What Sulfametoprim contains

The active substances are sulfamethoxazole and trimethoprim.

Each tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim.

The excipients are: microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate.

Content of the pack:

Carton box with 20 and 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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