PACKAGE LEAFLET: Information for the patient

BAKTRIM

Paediatric oral suspension

(200 mg + 40 mg) / 5 ml

(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 your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- 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 BAKTRIM IS AND WHAT IT IS USED FOR

Baktrim 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.

Baktrim paedriatic oral suspension 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, prosthatitis, gonorrhea;
- gastrointestinal tract infections, caused by *Salmonella typhi* and *paratyphi* etc., such as dysentery, traveler's diarrhea, typhoid and paratyphoid fever, cholera;
- skin infections; in bacterial complications of some pediatric infectious diseases, such as: measles, scarlatina, pertussis; chronic and acute osteomyelitis, acute brucellosis;
- 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 Baktrim 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 BAKTRIM

Do not give Baktrim to your child if:

- your child is hypersensitive to sulfonamides and trimethoprim or to any of the other excipients of the oral suspension;
- your child has severe impairment of liver parenchima;
- your child has blood dyscrasia or porphyria;
- your child has glucose-6-phosphate dehydrogenase deficiency;
- your child suffers of severe kidney failure.

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

Take special care with Baktrim

During long-term treatment, analysis of peripheral blood should be made, while for patients with renal function impairment, urine analysis and kidney function tests should be performed.
Treatment should be accompanied by large amounts of fluids, in order to prevent crystalluria and the formation of stones.
Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of sulfamethoxazole with trimethoprim. Additional signs to look for include: ulcers in the mouth, in the throat, in the genitals, and conjunctivitis. These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. If Stevens-Johnson syndrome or toxic epidermal necrolysis is developed during the use of Baktrim, the product should be interrupted immediately, and urgent advice from a doctor is necessary. In this case the patient must not be re-started on Baktrim at any time.
If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.

Ask your doctor before you give Baktrim to your child 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;
- it will be used in predisposed patients for hyperkalemia;
- if the patient has an infection caused by β-hemolytic streptococcus of A group.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Baktrim. Please contact your doctor or pharmacist if you are giving or have recently given to your child other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Baktrim if you have given any other drugs to your child 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 plasmatic proteins. At the same time, sulfamethoxazole reduces the metabolism of these drugs.
- The combination of Baktrim 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 Baktrim 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 sulfinpyrazone from its binding with plasmatic proteins, hence increasing its toxicity.
- Trimethoprim, either alone or combined with sulfamethoxazole, should not be combined with dofetilide, since the plasmatic concentration of the latter markedly increases.
- The risk for lactic acidosis by metformin markedly increases when it is combined with Baktrim.
- Simultaneous administration of Baktrim with pyrimethamine and methotrexate may increase the risk for pancytopenia and megaloblastic anemia.
- Baktrim 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 Baktrim in patients with renal disorders.

Important information about some of the excipients of Baktrim

Baktrim contains:

- methylhydroxybenzoate and propylhydroxybenzoate, which may cause allergic reactions (possibly delayed);
- sucrose; if you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving this medicinal product. It may be harmful to the teeth during its chronic use.

3. HOW TO TAKE BAKTRIM

Always give Baktrim to your child 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 Baktrim are too strong or too weak, talk to your doctor or pharmacist. Shake well before using.

Dosage is as follows:

Children:

240 mg every 12 hours in those aged from 2 - 5 years old.

480 mg every 12 hours in those aged from 6 - 12 years old.

If your child has taken more Baktrim

If your child has taken more Baktrim than he/she 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 advice for the actions to be taken.

If you forget to give Baktrim to your child

If you forget to give your child a dose (or more doses), give the next dose when it is time to take it usually.

Do not give 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, Baktrim may cause side effects, although not everybody manifests them. Baktrim is well tolerated in the recommended doses. Inform your doctor for the following side effects that may appear to your child:

- 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 Baktrim should be discontinued.

Other side effects:

- high levels of potassium in the blood;
- a fungal infection called candidiasis which can affect your child’s mouth or vagina.
- fever (high temperature) or frequent infections;
- inflammation of the eye which causes pain and redness;
- low levels of sodium in blood;
- heart problems;
- jaundice (the skin and the whites of the eyes turn yellow); this can occur at the same time as unexpected bleeding or bruising;
- arthritis;
- problems with the urine; passing more or less urine than usual; blood or cloudiness in the urine;
- kidney problems;
- ringing or other unusual sounds in the ears;

- depression;
- muscle pain and/or muscle weakness;
- loss of appetite;
- cough;
- psychotic disorders (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 BAKTRIM

Keep out of the reach and sight of children.

Do not use Bakrim 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 Baktrim contains

The active substances are sulfamethoxazole and trimethoprim.

5 ml of oral suspension contain 200 mg of sulfamethoxazole and 40 mg of trimethoprim.

The excipients are: sucrose, microcrystalline cellulose and carboxymethylcellulose sodium, ammonium glycyrrhizinate, methyl hydroxybenzoate, propyl hydroxybenzoate, saccharin sodium, polysorbate, disodium EDTA, banana essence, glycerol, ethanol, purified water.

Content of the pack:

Carton box with one glass bottle of 100 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in January 2024.