PACKAGE LEAFLET: Information for the patient

BAKTRIM FORTE

Tablets – 800 mg / 160 mg

(Sulfamethoxazole and 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 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 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 FORTE IS AND WHAT IT IS USED FOR

Baktrim Forte is a combination of two active substances (sulfamethoxazole and trimethoprim) which together inhibit the metabolism of the bacterium, thereby exerting a bactericidal effect.

Baktrim Forte tablets are used in adults, adolescents and children aged 6 years and over.

Baktrim Forte is mainly used for various infections of the urinary tract and prostate and also following deterioration of chronic respiratory infection. Other infections (such as dysentery, typhoid and paratyphoid fever) can also be treated with Baktrim Forte.

Baktrim Forte is additionally used in the prevention and treatment of infections caused by *Pneumocystis jirovecii*, especially in patients with a weakened immune system.

2. BEFORE YOU TAKE BAKTRIM FORTE

Do not take Baktrim Forte if you:

- are hypersensitive (allergic) to trimethoprim, sulfamethoxazole or any of the other ingredients of Baktrim Forte;
- have severe liver damage or a blood disorder;
- have severely impaired kidney function;
- are being treated with dofetilide (used for cardiac rhythm disturbances).

Baktrim Forte must not be used in infans under 6 weeks of age.

Take special care with Baktrim Forte

- If you have impaired kidney function or folic acid deficiency, you should ask your doctor for advice before commencing treatment with Baktrim Forte.
- You must also ask your doctor for advice before commencing treatment with Baktrim Forte if you are over 65 years old, malnourished or severely dehydrated.
- If you have cystic fibrosis, you should ask your doctor for advice before commencing treatment with Baktrim Forte.
- If you unexpectedly get a worsened cough and shortness of breath, you must contact a doctor immediately.

There have rare reports of severe immune response due to uncontrolled activation of white blood corpuscles resulting in inflammation (hemophagocytic lymphohistiocytis), which can be life-threatening without early diagnosis and treatment. If you develop various symptoms such as fever, swollen glands, lassitude, dizziness, shortness of breath, bruising or skin rash at the same time or following a short interval, you must contact a doctor immediately.

In rare cases, Baktrim Forte may affect the white blood cells, thereby weakening the body's defence against infections. If you develop an infection with symptoms such as fever

accompanied by severely impaired general condition or fever with symptoms of local infection such as a sore throat/pharynx/mouth or urinary problems, you must see your doctor as soon as possible so that blood tests can be performed to rule out a shortage of white blood cells (agranulocytosis). It is important that you tell him/her about your medication.

Although it is very rare, cases with a fatal outcome have been reported in connection with side effects such as blood diseases, severe skin reactions such as Stevens-Johnson syndrome [SJS], drug-induced rashes with an increased number of white blood cells (eosinophilia) and systemic symptoms [DRESS] and toxic epidermal necrolysis [TEN, an immunological reaction which can result in the skin peeling off] and acute generalised exanthematous pustulosis [AGEP]; and acute liver failure, have been reported in patients using trimethoprim and sulfamethoxazole. This may begin as reddish-violet, target-like or round patches with central blistering, which are often spread symmetrically over the body.

Other signs to watch out for are ulcers of the mouth, throat, nose or genitalia and eye inflammation (red and swollen eyes).

These potentially life-threatening skin reactions are often followed by flu-like symptoms. The rashes may develop into blisters over large areas or result in peeling-off of the skin.

The risk of serious skin reactions is greatest during the first few weeks of treatment.

If you develop Stevens-Johnson syndrome, DRESS, AGEP or TEN after using trimethoprim and sulfamethoxazole, which are present in Baktrim Forte, you must never use medicines that contain trimethoprim and sulfamethoxazole again.

If you develop rashes or signs of these skin reactions, you must stop taking Baktrim Forte at once and immediately contact your doctor and tell him/her that you are taking this medicine.

Stop taking Baktrim Forte and contact your doctor immediately if you develop any of the following symptoms (angioedema):

- swelling of the face, tongue or throat;
- difficulties swallowing;
- nettle rash and breathing difficulty.

Stop taking Baktrim Forte and contact your doctor as soon as possible if you develop inexplicable muscle pain, muscle cramps or muscle weakness.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines. The efficacy of Baktrim Forte may affect or be affected if it is taken at the same time as certain other medicines, such as:

- chlorpropamide, glibenclamide, repaglinide, pioglitazone and glipizide (for age-related diabetes);
- memantine (for dementia);
- warfarin (anticoagulant);
- ciclosporin, tacrolimus and azathioprine (immunosuppressants);
- prednisolone (anti-inflammatory);
- phenytoin (antiepileptic);
- digoxin, amiodarone (heart medicines);
- ACE inhibitors (for high blood pressure);
- tricyclic antidepressants, clozapine (for psychosis);
- contraceptive pills;
- zidovudine and lamivudine (for HIV);
- thiazides, potassium sparing diuretics;
- methotrexate, paclitaxel and mercaptopurine (anti-cancer drugs);
- pyrimethamine (antimalarial).

Baktrim Forte must not be given concurrently with dofetilide, which is used to treat cardiac rhythm disturbances.

Ask your doctor for advice before using other medicines concurrently.

Pregnancy and Breastfeeding

Baktrim Forte must not be used during pregnancy unless the doctor has said so.
There is a risk that the fetus may be affected.

Baktrim Forte must not be used during breastfeeding unless the doctor has said so.
This medicine passes into breast milk.

Driving and using machines

Although no studies have been carried out, Baktrim Forte is not expected to have any effect on the ability to drive and use machines.

Important information about some of the excipients of Baktrim Forte

Baktrim Forte tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

3. HOW TO TAKE BAKTRIM FORTE

Always take this medicine exactly as your doctor or pharmacist has told you. **Never change the dose that has been prescribed yourself and never discontinue the treatment without consulting your doctor.** Check with your doctor or pharmacist if you are not sure.

Standard dose for adults and children over 12 years of age: 1 tablet morning and evening.
For long-term treatment: 1 tablet per day.
The tablet may be divided into two equal doses.

Drink plenty of liquids, e.g. water, when you take Baktrim Forte in order to prevent problems with crystals in your urine and urinary stones; see section 4.

If you take more Baktrim Forte than you should

If you have taken too much medicine or for instance if a child has mistakenly consumed the medicine, contact your doctor or hospital immediately for assessment of the risk and advice.

If you forget to take Baktrim Forte

Try to take Baktrim Forte daily as prescribed. However, if you miss a dose, do not take an extra dose, just resume your usual schedule.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Severe side effects

Stop taking Baktrim Forte and contact your doctor straight away or go to your nearest emergency department if you get any of the following symptoms:

Extremely strong and severe skin side effects such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in conjunction with use of Baktrim Forte. The skin side effects may consist of a rash with or without blisters. Skin redness, ulcers or swelling of the mouth, throat, eyes, nose and around the sexual organs (Stevens-Johnson syndrome), oedema (DRESS) and fever and flu-like symptoms may also occur.

The skin rash may develop into severe extensive skin damage (skin-peeling of the epidermis and superficial mucous membranes) with life-threatening consequences.

Other side effects that may occur:

<u>Common (occurring in more than 1 in 100 patients):</u>

- nausea;
- vomiting;
- elevated liver enzymes (seen in blood tests);
- elevated renal enzymes (seen in blood tests);
- skin rash;

- skin inflammation and skin redness;
- itching.

Uncommon (occurring in more than 1 in 1,000 patients):

- fungal infections;
- seizures;
- diarrhoea;
- colitis;
- hepatitis;
- renal impairment;
- nettle rash.

Rare (occurring in more than 1 in 10,000 but less than 1 in 1,000 patients):

- effect on blood chemistry (e.g. agranulocytosis, see “Take special care with Baktrim Forte”);
- reduced blood sugar levels;
- functional neurological disturbances;
- inflammation of the tongue and oral mucosa;
- cholestasis;
- crystals in the urine;
- vasculitis;
- vascular pain.

Very rare (occurring in less than 1 in 10,000 patients):

- hypersensitivity reactions such as angioedema (see “Take special care with Baktrim Forte”);
- effect on the lungs, e.g. cough, shortness of breath;
- increased blood potassium levels;
- hallucinations;
- difficulty coordinating muscle movements;
- eye inflammation;
- dizziness;
- allergic reaction with inflammation of the heart muscle (allergic myocarditis);

- ringing in the ears;
- liver necrosis (death of liver tissue);
- partial inflammation of the kidney;
- passing more urine than usual;
- meningitis;
- photosensitivity;
- vasculitis affecting the whole body;
- destruction of muscle fibres (rhabdomyolysis, see "Take special care with Baktrim Forte").

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

- reduced blood sodium levels;
- acute pancreatitis;
- vanishing bile duct syndrome;
- joint and muscle pain;
- plum-coloured, raised and painful lesions on limbs and sometimes on the face and neck accompanied by fever (Sweet's syndrome);
- kidney stones (urolithiasis).

5. HOW TO STORE BAKTRIM FORTE

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

Do not use this medicine after the expiry date which is stated on the blister and on the carton.

Do not store above 25ºC.

Store in the original packaging to protect it from light.

6. FURTHER INFORMATION

What Baktrim Forte 800 mg / 160 mg tablets contain:

The active substances are sulfamethoxazole and trimethoprim.

Each tablet contains 800 mg sulfamethoxazole and 160 mg trimethoprim.

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

Content of the pack: Box with 10 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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This leaflet was formulated in April 2024.