Package leaflet: Information for the user

Bactrim 400 mg/80 mg tablets
Bactrim forte 800 mg/160 mg tablets

sulfamethoxazole and trimethoprim

Read all of this leaflet carefully before you start using 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Bactrim/Bactrim forte is and what it is used for

Bactrim/Bactrim forte is a combination of two substances (sulfamethoxazole and trimethoprim) which together inhibit the metabolism of the bacterium, thereby exerting a bactericidal effect.

Bactrim/Bactrim forte tablets are used in adults, adolescents and children aged 6 years and over.

Bactrim/Bactrim 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 Bactrim/Bactrim forte.
Bactrim/Bactrim forte is additionally used in the prevention and treatment of infections caused by *Pneumocystis jirovecii*, especially in patients with a weakened immune system. Bactrim forte contains double the amount of active substance present in Bactrim.

2. What you need to know before you take Bactrim/Bactrim forte

Do not use Bactrim/Bactrim forte
- if you are hypersensitive (allergic) to trimethoprim, sulfamethoxazole or any of the other ingredients of Bactrim/Bactrim forte;
- if you have severe liver damage or a blood disorder;
- Bactrim/Bactrim forte must not be used in children under 6 weeks of age;
- if you have severely impaired kidney function;
- if you are being treated with dofetilide (used for cardiac rhythm disturbances).

Warnings and precautions
- If you have impaired kidney function or folic acid deficiency, you should ask your doctor for advice before commencing treatment with Bactrim/Bactrim forte.

- You must also ask your doctor for advice before commencing treatment with Bactrim/Bactrim 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 Bactrim/Bactrim 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, swlooen 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, Bactrim 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 Bactrim, 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 Bactrim at once and immediately contact your doctor and tell him/her that you are taking this medicine.

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

Other medicines and Bactrim/Bactrim forte
Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines. The efficacy of Bactrim/Bactrim forte may affect or be affected if Bactrim/Bactrim forte is taken at the same time as certain other medicines.
This applies to:

- 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)

Bactrim 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 breast-feeding
Bactrim/Bactrim forte must not be used during pregnancy unless the doctor has said so.
There is a risk that the fetus may be affected.
Bactrim/Bactrim forte must not be used during breastfeeding unless the doctor has said so.
Bactrim/Bactrim forte passes into breast milk.

Driving and using machines:
Although no studies have been carried out, Bactrim/Bactrim forte is not expected to have any effect on the ability to drive and use machines.

Bactrim/Bactrim forte contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Bactrim/Bactrim forte

Always use Bactrim/Bactrim forte as directed by your doctor. **Never change the dose that has been prescribed yourself and never discontinue the treatment without consulting your doctor.** Ask your doctor or pharmacist for advice if you are unsure.

Bactrim:
Standard dose for adults and children over 12 years of age: 2 Bactrim tablets morning and evening
Standard dose for children under 12 years of age:
Children aged 6 to 12 years: 1 Bactrim tablet morning and evening.
The tablet may be divided into two equal doses.

Bactrim forte:
Standard dose for adults and children over 12 years of age: 1 Bactrim forte tablet morning and evening

For long-term treatment: 1 tablet per day
The tablet may be divided into two equal doses.

Drink plenty of water, e.g. water, when you take Bactrim or Bactrim forte in order to prevent problems with crystals in your urine and urinary stones, see section 4.

If you take more Bactrim/Bactrim 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, hospital or the Poisons Information Centre (Tel 112) immediately for assessment of the risk and advice.

If you forget to take Bactrim/Bactrim forte:
Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Bactrim/Bactrim forte can cause side effects, although not everybody gets them.

Severe side effects

Stop taking Bactrim/Bactrim 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 Bactrim/Bactrim 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 potential side effects

Common (occurring in more than 1 in 100 patients):
- nausea
- vomiting
- elevated liver values (seen in blood tests)
- elevated renal values (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 "Be especially careful with Bactrim/Bactrim 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 "Be especially careful with Bactrim/Bactrim 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 "Be especially careful with Bactrim/Bactrim forte")

Frequency not known (cannot be calculated 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)

Reporting of side effects
Talk to your doctor, pharmacist or nurse if you develop side effects. This also applies to side effects not mentioned in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Medical Products Agency
Box 26
751 03 Uppsala
Website: www.lakemedelsverket.se

5. How to store Bactrim/Bactrim 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 carton. The expiry date refers to the last day of that month.
Bactrim/Bactrim forte must be stored in the original package.

Do not throw away this medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bactrim/Bactrim forte contains:

- The active substances are sulfamethoxazole and trimethoprim.
  1 *Bactrim* tablet contains sulfamethoxazole 400 mg and trimethoprim 80 mg.

  1 *Bactrim forte* tablet contains sulfamethoxazole 800 mg and trimethoprim 160 mg.

- The other ingredients are as follows:

Bactrim tablets: povidone K30, sodium starch glycolate, magnesium stearate, docusate sodium
Bactrim forte tablets: povidone K30, sodium starch glycolate, magnesium stearate, docusate sodium

What Bactrim/Bactrim forte looks like and contents of the pack:
Bactrim: blister pack with 20 tablets
White to off-white, round, biconvex tablet, approx. 11 mm in diameter, marked with 'BACTRIM' on one side and a score line on the other side.

Bactrim forte: blister pack with 50 tablets
White to off-white, oblong, biconvex tablet, approx. 19 mm long and 9 mm wide, marked with 'BACTRIM 800+160' on one side and a score line on the other side.

Marketing Authorisation Holder and Manufacturer:

EUMEDICA Pharmaceuticals GmbH
Basler Straße 126
79540 Lörrach
Germany

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*Formerly Roche AB