

## **Package leaflet: Information for the user**

### **Bactrim 40 mg/ml + 8 mg/ml oral suspension** 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 is and what it is used for
2. What you need to know before you take Bactrim
3. How to take Bactrim
4. Possible side effects
5. How to store Bactrim
6. Contents of the pack and other information

#### **1. What Bactrim is and what it is used for**

##### **What Bactrim is**

Bactrim is a combination of two substances - sulfamethoxazole and trimethoprim. Together they destroy the bacteria and stop them from being able to grow and reproduce.

##### **What Bactrim is used for**

Bactrim is mainly used for:

- infections of the urinary tract
- infections of the prostate
- lung infections which get worse over time
- infections such as dysentery, typhoid and paratyphoid fever

Bactrim can also be used to prevent and treat a type of pneumonia caused by a yeast-like fungus called '*Pneumocystis jirovecii*'. Here, it is used especially in patients with a weak immune system.

Bactrim is used in adults and children aged 6 weeks and over.

#### **2. What you need to know before you take Bactrim**

##### **Do not use Bactrim if:**

- you are allergic to trimethoprim, sulfamethoxazole or any of the other ingredients of Bactrim - see section 6 'What Bactrim contains'
- you have severe liver damage
- you have a severe blood disease
- your body is unable to break down glucose, or you are breastfeeding a baby whose body is unable to break down glucose
- a child is under 6 weeks of age
- you have severe kidney insufficiency
- you are taking the medicine dofetilide (used for heartbeat problems)

Do not use Bactrim if any of the above apply to you. If you are not sure, talk to your doctor before using Bactrim.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Bactrim if:

- you have kidney problems
- you have low levels of folic acid
- you are over 65 years old, malnourished or very dehydrated.
- you have cystic fibrosis
- you have severe allergy or asthma
- you have thyroid gland dysfunction
- you have been told that you are person whose liver takes longer to clear medications
- you have been told by your doctor that you have a lot of potassium in your blood

### **Look out for side effects**

Stop taking Bactrim and tell your doctor straight away if you notice any of the following side effects:

- **Infection:** Bactrim can reduce your defences against infection (by affecting white blood cells). If you get signs of infection, you must see your doctor as soon as possible – see section 4 under ‘Serious side effects’ for the signs of infection.
- **Potentially life-threatening skin reactions:** such as, Stevens-Johnson syndrome, Drug-induced Rashes with an increased number of white blood cells (Eosinophilia) and Systemic Symptoms (DRESS), Toxic Epidermal Necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP) see section 4 for the signs of these problems under ‘Serious side effects’.
- **Muscle pain, cramps or weakness:** Stop taking Bactrim and tell your doctor straight away if you get any of the above. It is important to tell them that you have been taking Bactrim.
- **Cough and shortness of breath:** If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.
- **Haemophagocytic lymphohistiocytosis:** There have been very rare reports about excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations (haemophagocytic lymphohistiocytosis), which can be life-threatening if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay, contact your doctor immediately.

### **Other medicines and Bactrim**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines. Bactrim can affect the way some medicines work. Also, some other medicines can affect the way Bactrim works.

In particular, do not take Bactrim if you are taking dofetilide, a medicine used for heart beat problems.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines for type 2 diabetes such as: chlorpropamide, glibenclamide, repaglinide, pioglitazone, and glipizide, tolbutamine, gliclazide, rosiglitazone
- memantine, amantadine (for dementia)
- warfarin, acenocoumarol, phenprocoumon (to thin the blood)
- ciclosporin, tacrolimus and azathioprine (medicines to suppress your immune system)
- prednisolone (anti-inflammatory)
- phenytoin (for epilepsy)
- digoxin, amiodarone (heart medicines)
- ACE inhibitors (for high blood pressure or heart failure)
- tricyclic antidepressants, clozapine (for mental health problems)
- contraceptive pills

- zidovudine and lamivudine (for HIV)
- water tablets such as thiazides, potassium sparing diuretics (for high blood pressure or heart failure)
- methotrexate, paclitaxel and mercaptopurine (anti-cancer medicines)
- pyrimethamine (anti-malarial medicines)
- dapsone (for skin condition)

Bactrim may interfere with some medical tests. Tell your doctor that you are taking Bactrim if you are told you need any medical tests whilst taking Bactrim.

If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before using Bactrim.

### **Pregnancy and breast-feeding**

If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you take this medicine. There is a risk that the baby may be affected.

You should ask your doctor or your pharmacist if you are breast-feeding or planning to breast-feed. This is because small amounts of Bactrim may pass onto the baby.

### **Driving and using machines**

Bactrim is not expected to affect your ability to drive and use machines although <Tradename can cause dizziness, fits and hallucinations (see section 4).

### **Bactrim contains sorbitol (E 420), methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), propylene glycol (E 1520), alcohol (ethanol) and sodium.**

Bactrim contains 630 mg sorbitol per ml corresponding to 3 to 25 grams sorbitol per day.

Sorbitol is a source of fructose. If you (or your child) do not tolerate certain sugars, or you (or your child) have been diagnosed with hereditary fructose intolerance, a rare, hereditary disease that prevents fructose from being broken down, consult a doctor before using this medicine.

Sorbitol can cause stomach / intestinal discomfort and can have a mild laxative effect.

Bactrim contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause an allergic reaction (possibly delayed).

Bactrim contains 24 mg of propylene glycol per 5 ml equivalent to 4.8 mg/ml.

Bactrim contains 9 mg of alcohol (ethanol) per 5 ml equivalent to 1.8 mg/ml. The amount per 5 ml of this medicine is equivalent to less than 0.23 ml of beer or 0.10 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Bactrim contains less than 1 mmol sodium (23 mg) per ml and is essentially 'sodium-free'.

## **3. How to take Bactrim**

Always use Bactrim as directed by your doctor. **Do not change the dose that has been prescribed.** Ask your doctor or pharmacist for advice if you are unsure.

### **When to take Bactrim**

Bactrim comes with a measuring spoon graduated 1.25ml, 2.5ml, and 5ml. This spoon can also be used to measure 2.5ml (one half of a spoon). Always use the spoon that is provided when taking Bactrim.

Take Bactrim twice a day - once in the morning and once in the evening.

For oral use.

Shake the bottle before each use.

Rinse the spoon after each use.

### **How much to take**

#### **Standard dose for adults and children over 12 years of age:**

- 20 ml (4 spoons) Bactrim oral suspension, morning and evening

#### **Standard dose for children aged 12 years or under:**

- 6 weeks to 5 months: 2.5 ml (one half of a spoon) oral suspension, morning and evening.
- 6 months to 5 years: 5 ml (1 spoon) oral suspension, morning and evening.
- 6 to 12 years: 10 ml (2 spoons) oral suspension, morning and evening.

Your treatment will last until you are symptom-free for 2 days and it normally should not exceed 7 days. Talk to your doctor if you do not feel better or feel worse after 7 days of therapy.

Your doctor may prescribe a different dose or duration of treatment based on your diagnosis and clinical features. Always follow the prescriber's advice.

### **If you take more Bactrim than you should**

If you take more Bactrim than you should, notify your doctor immediately or go to the nearest hospital.

Symptoms of an overdose can consist of nausea, vomiting, diarrhea, headache, dizziness, mental and visual disturbances. The doctor will establish adequate supportive treatment to treat symptoms of excessive dosage.

### **If you forget to take Bactrim:**

- If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose and take your next dose as normal.
- Do not take a double dose to make up for a forgotten dose.

## **4. Possible side effects**

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

### **Serious side effects**

Stop taking Bactrim and contact your doctor straight away if you get any of the below:

- **Potentially life-threatening skin reactions:** (frequency: very rare)
  - These skin reactions can often start with flu-like symptoms.
  - The risk is greatest during the first weeks of treatment.
  - Signs of skin reactions include:
    - red to violet, target-like or round patches with blisters in the middle - often spread symmetrically over the body. The skin may start to peel off.
    - sudden skin eruptions of red, pinhead-sized pustules (acute generalized exanthematous pustulosis (AGEP))
    - ulcers of the mouth, throat, nose or genitals
    - eye inflammation (red and swollen eyes)
- Do not use medicines that contain trimethoprim or sulfamethoxazole again, if you get any of the above after using Bactrim.
- **Muscle pain, cramps or weakness** (myalgia, frequency: not known)
  - Pain, cramps or weakness you cannot explain.
- **Severe infection:** your doctor must do a blood test as soon as possible to rule out a shortage of white blood cells (agranulocytosis, frequency: very rare). Look out for signs of:
  - infection with fever and generally feeling unwell
  - sore throat or mouth
  - urinary tract infection

- **Severe allergic reaction** (frequency: very rare):
  - swelling of the face, tongue or throat, difficulty swallowing
  - nettle rash and facial disorders

Stop taking Bactrim and contact your doctor straight away if you get any of the above.

### **Other side effects**

Tell your doctor, pharmacist or nurse if you experience any of the following side effects:

**Common:** may affect up to 1 in 10 people

- feeling sick or being sick
- blood tests showing liver or kidney problems
- inflamed skin or rash, redness or itching

**Uncommon:** may affect up to 1 in 100 people

- fungal infections
- fits (seizures)
- diarrhoea
- colitis
- inflamed liver (hepatitis)
- kidney failure
- nettle rash

**Rare:** may affect up to 1 in 1,000 people:

- blood problems such as low white blood cells
- reduced blood sugar levels
- feeling weak, difficulty moving, blackouts (functional neurological disturbances)
- inflamed tongue and mouth
- bile problems (cholestasis)
- crystals in the urine
- pain in the stomach.

**Very rare:** may affect up to 1 in 10,000 people

- lung problems such as cough, shortness of breath
- blood tests showing increased blood potassium levels
- hallucinations
- difficulty coordinating muscle movements
- inflamed eye
- dizziness
- allergic reaction with inflamed heart muscle (allergic myocarditis)
- ringing in the ears
- death of liver tissue (liver necrosis)
- passing more urine than usual or partly inflamed kidney
- meningitis
- sensitivity to light (photosensitivity)
- inflamed blood vessels (vasculitis) affecting the whole body
- breakdown of muscle fibres (rhabdomyolysis).

**Not known:** it is not known how often these happen

- blood tests showing reduced sodium levels
- sudden inflammation of the pancreas (acute pancreatitis)
- injury to the bile ducts (vanishing bile duct syndrome)
- joint and muscle pain

- plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome)
- renal stones (urolithiasis)

Your doctor may ask you to have blood tests whilst you are taking Bactrim to monitor some of these side effects.

Tell your doctor, pharmacist or nurse if you notice any of the side effects listed above.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Bactrim**

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.

Once opened do not store above 25 °C and use within 8 weeks.

Keep the measuring spoon with the product in the outer packaging.

- 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 contains:**

- The active substances are sulfamethoxazole and trimethoprim.  
1 ml Bactrim oral suspension contains sulfamethoxazole 40 mg and trimethoprim 8 mg.  
One spoonful of 5 ml *Bactrim oral suspension* contains sulfamethoxazole 200 mg and trimethoprim 40 mg.
- The other ingredients are as follows: Sorbitol (sweetening agent E 420), microcrystalline cellulose, carmellose sodium, methyl parahydroxybenzoate (preservative E 218), propyl parahydroxybenzoate (preservative E 216), polysorbate 80, banana flavouring (contains propylene glycol (E 1520)), vanilla flavouring (contains ethanol) and purified water.

### **What Bactrim looks like and contents of the pack:**

Glass bottle with 100 ml oral suspension

A clear, plastic 5ml measuring spoon graduated 1.25 ml, 2.5 ml, and 5 ml.

### **Marketing Authorisation Holder and Manufacturer:**

EUMEDICA Pharmaceuticals GmbH  
Basler Straße 126  
79540 Lörrach  
Germany

### **This medicine is authorised in the Member States of the European Economic under the following names:**

Sweden, France	Bactrim
Italy	Bactrimel

**This leaflet was last revised on 2023-05-11**

**Advice/medical education**

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.