

Summary Public Assessment Report

Bactrim (trimethoprim, sulfamethoxazole)

SE/H/1914/01/MR

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Bactrim
trimethoprim, sulfamethoxazole

Oral suspension, 40 mg/ml + 8 mg/ml

This is a summary of the public assessment report (PAR) for Bactrim. It explains how Bactrim was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Bactrim.

For practical information about using Bactrim, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bactrim and what is it used for?

Bactrim is used in the treatment of:

- 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.

How does Bactrim work?

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.

How is Bactrim used?

The pharmaceutical form of Bactrim is oral suspension.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Bactrim have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Bactrim is effective in treating upper urinary tract infections, complicated lower urinary tract infections, prostatitis, serious infections originating from the urinary tract, acute exacerbation of chronic bronchitis, shigellosis, typhoid and paratyphoid fever, prophylaxis

and treatment of infections caused by *Pneumocystis jirovecii*, particularly in severely immunocompromised patients.

What are the possible side effects of Bactrim?

For the full list of all side effects reported with Bactrim, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Bactrim approved?

It was noted that the effect of Bactrim in the treatment of upper urinary tract infections, complicated lower urinary tract infections, prostatitis, serious infections originating from the urinary tract, acute exacerbation of chronic bronchitis, shigellosis, typhoid and paratyphoid fever, prophylaxis and treatment of infections caused by *Pneumocystis jirovecii*, particularly in severely immunocompromised patients is considered well-established since the product has been approved and used in clinical practice for over 45 years.

Therefore, the Medical Products Agency in Sweden decided that Bactrim's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Bactrim?

A risk management plan has been developed to ensure that Bactrim is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bactrim, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Bactrim

The full PAR for Bactrim can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Bactrim, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-04.