

PACKAGE LEAFLET: INFORMATION FOR THE USER

BACTRIM

tablets

CO-TRIMOXAZOLE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What Bactrim is and what it is used for
2. Before you take Bactrim
3. How to take Bactrim Tablets
4. Possible side effects
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1 WHAT BACTRIM IS AND WHAT IT IS USED FOR

Bactrim Tablets (called 'Bactrim' in this leaflet) are made up of two different medicines called sulfamethoxazole and trimethoprim. These medicines are sometimes given the combined name co-trimoxazole. Both belong to a group of medicines called antibiotics. They are used to treat infections caused by bacteria. Like all antibiotics, Bactrim only works against some types of bacteria.

This means that it is only suitable for treating some types of infections. Bactrim can be used to treat or prevent:

- lung infections (pneumonia or PCP) caused by a bacteria called *Pneumocystis jiroveci* (previously known as *Pneumocystis carinii*)
- infections caused by a bacteria called *Toxoplasma* (toxoplasmosis). Bactrim can be used to treat:
- bladder or urinary tract infections (water infections)
- lung infections such as bronchitis
- ear infections such as otitis media
- an infection called nocardiosis, it can affect the lungs, skin and brain.

2 BEFORE YOU TAKE BACTRIM

Do not take Bactrim if:

- you are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of Bactrim

- you are allergic to sulphonamide medicines. Examples include sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet)
- you have liver or kidney problems
- you have ever had a problem with your blood
- it is for your child and they are less than 6 weeks old or were premature. Unless it is for the treatment or prevention of PCP. In this case, babies should be at least 4 weeks old.

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

Take special care with Bactrim

Before you take Bactrim, tell your doctor or pharmacist if:

- you have severe allergies or asthma
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Bactrim appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
- these potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.
- the highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
- if you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Bactrim you must not be re-started on Bactrim at any time.
- if you develop a rash or these skin symptoms, stop taking Bactrim, seek urgent advice from a doctor and tell him that you are taking this medicine.
- you have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system
- you don't have enough folic acid (a vitamin) in your body - which can make your skin pale and make you feel tired, weak and breathless. This is known as anaemia
- you have ever had jaundice which can cause yellowing of your skin or the whites of your eyes
- you have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition
- you are elderly
- you are underweight or malnourished
- you have been told by your doctor that you have a lot of potassium in your blood.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Bactrim can affect the way some medicines work. Also some other medicines can affect the way Bactrim works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Diuretics (water tablets), which help increase the amount of urine you produce
- Pyrimethamine, used to treat and prevent malaria, and to treat diarrhoea
- Ciclosporin, used after transplant operations or for your immune system
- Medicines used to thin the blood such as warfarin
- Phenytoin, used to treat epilepsy (fits)
- Medicines for diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas)
- Medicines to treat problems with the way your heart beats such as digoxin or procainamide
- Amantadine, used to treat Parkinson's disease, multiple sclerosis, 'flu or shingles
- Medicines to treat HIV (Human Immunodeficiency Virus), called zidovudine or lamivudine
- Medicines that can increase the amount of potassium in your blood, such as diuretics (water tablets, which help increase the amount of urine you produce), steroids (like prednisolone) and digoxin
- Methotrexate, a medicine used to treat cancer or for your immune system. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Bactrim.

Taking Bactrim with food and drink

You should take Bactrim with some food or drink. This will stop you feeling sick (nausea) or having diarrhoea. Although it is better to take it with food, you can still take it on an empty stomach. Drink plenty of fluid such as water while you are taking Bactrim.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to get pregnant, or breast-feeding.

3 HOW TO TAKE BACTRIM TABLETS

Always take Bactrim exactly as your doctor has told you. The label on your pack will tell you how much to take and how often to take it. You should check with your doctor or pharmacist if you are not sure.

Usual Dose

Adults and children over 12 years

- The usual dose is two tablets in a morning and two tablets in an evening.
- Bactrim should be taken for at least five days.
- Make sure that you finish the course of Bactrim which your doctor has prescribed.

Bactrim Tablets are not usually given to children under 12 years old. If they have been given to your child please speak to your doctor or pharmacist for more information.

Special Dose

The dose of Bactrim and how long you need to take it depends on the infection you have and how bad it is. Your doctor may prescribe you a different dose or length of course of Bactrim to

- treat urinary tract (water) infections
- treat and prevent lung infections caused by the bacteria *Pneumocystis jiroveci*
- treat infections caused by the bacteria *Toxoplasma* (toxoplasmosis) or *Nocardia* (nocardiosis).

If you have kidney problems your doctor may

- prescribe a lower dose of Bactrim
- take blood to test whether the medicine is working properly. If you take Bactrim for a long time your doctor may
- take blood to test whether the medicine is working properly
- prescribe folic acid (a vitamin) for you to take at the same time as Bactrim.

If you take more Bactrim than you should

If you take more Bactrim than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you.

If you have taken too much Bactrim you may

- feel or be sick
- feel dizzy or confused.

If you forget to take Bactrim

- If you forget to take a dose, take it as soon as you remember it.
- Do not take a double dose to make up for the forgotten dose.

4 POSSIBLE SIDE EFFECTS

Like all medicines Bactrim can cause side effects, although not everybody gets them. You may experience the following side effects with this medicine.

Stop taking Bactrim and tell your doctor immediately if you have an allergic reaction. Chances of an allergic reaction is very rare (fewer than 1 in 10,000 people are affected), signs of an allergic reaction include

Allergic reactions

- Difficulty in breathing
- Fainting
- Swelling of face
- Swelling of mouth, tongue or throat which may be red and painful and/or cause difficulty in swallowing
- Chest pain
- Red patches on the skin

Very Common (more than 1 in 10 people)

- High levels of potassium in your blood, which can cause abnormal heart beats (palpitations).

Common (less than 1 in 10 people)

- An infection called thrush or candidiasis which can affect your mouth or vagina. It is caused by a fungus
- Headache
- Feeling sick (nausea)
- Diarrhoea
- Skin rashes.

Uncommon (less than 1 in 100)

- Being sick (vomiting).

Very Rare (less than 1 in 10,000 people)

- Fever (high temperature) or frequent infections
- Sudden wheeziness or difficulty breathing
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see Take special care with Bactrim).
- Mouth ulcers, cold sores and ulcers or soreness of your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on your skin or inside your mouth, nose, vagina or bottom
- Inflammation of the eye which causes pain and redness
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Low levels of sodium in your blood
- Changes in blood tests
- Feeling weak, tired or listless, pale skin (anaemia)
- Heart problems
- Jaundice (the skin and the whites of your eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising
- Pains in your stomach, which can occur with blood in your faeces (poo)
- Pains in your chest, muscles or joints and muscle weakness
- Arthritis
- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual. Blood or cloudiness in your urine.
- Kidney problems
- Sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- Problems controlling your movements
- Fits (convulsions or seizures)
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears
- Tingling or numbness in your hands and feet

- Seeing strange or unusual sights (hallucinations)
- Depression
- Muscle pain and/or muscle weakness in HIV patients.

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.

5 HOW TO STORE BACTRIM

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not take the tablets after the expiry date shown on the bottle label and carton.
- Store in the original package with this leaflet.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Leaflet date: February 2015