

PACKAGE LEAFLET: INFORMATION FOR THE USER
SEPTRIN® 160mg/800mg FORTE TABLETS
CO-TRIMOXAZOLE 160mg/800mg FORTE TABLETS
(co-trimoxazole)

This medicine is available as any of the above names but will be referred to as Septrin throughout the following leaflet. **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. See section 4.

What is in this leaflet:

1. What Septrin is and what it is used for
2. What you need to know before you take Septrin
3. How to take Septrin
4. Possible side effects
5. How to store Septrin
6. Contents of the pack and other information

1. WHAT SEPTRIN IS AND WHAT IT IS USED FOR

Septrin is a combination of two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain bacteria. This medicine combination is also named as co-trimoxazole. Like all antibiotics, Septrin only works against some types of bacteria. This means that it is only suitable for treating some types of infections. Septrin can be used to treat or prevent:

- Lung infections (pneumonia or PJP) caused by a bacteria called *Pneumocystis jirovecii* (previously known as *Pneumocystis carinii* or PCP).
- Infections caused by a bacteria called Toxoplasma (toxoplasmosis).

Septrin can be used to treat:

- Urinary bladder or urinary tract infections (water infections)
- Respiratory tract infections such as bronchitis
- Ear infections such as otitis media
- An infection called nocardiosis which can affect the lungs, skin and brain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SEPTRIN

Do not take Septrin if:

- You are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of Septrin (see section 6: Contents of the pack and other information).
- 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 severe liver or kidney problems.
- You have ever had a problem with your blood causing bruises or bleeding (thrombocytopenia).
- You have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system.

If it is for your child, Septrin should not be given if they are less than 6 weeks old or were premature unless it is for the treatment or prevention of PJP. In this case, Septrin should not be given if they are less than 4 weeks old.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Septrin:

- 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 Septrin 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 Septrin you must not be re-started on Septrin at any time.
- If you develop a rash or these skin symptoms, stop taking Septrin, seek urgent advice from a doctor and tell him that you are taking this medicine.
- If you have been told that you are at risk for a rare blood disorder called porphyria.
- If you have a kidney disease.
- If 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.
- If you have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells. If you have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition.
- If you are elderly.
- If you are underweight or malnourished.
- If you have been told by your doctor that you have a lot of potassium in your blood.
- If you have a severe blood disorder, such as a low number of red blood cells (anaemia), a low number of white blood cells (leucopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).

Other medicines and Septrin

Tell your doctor or pharmacist if you are taking, have recently taken or may take any other medicines. This is because Septrin can affect the way some medicines work. Also some other medicines can affect the way Septrin 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 organ transplant surgeries.
- Blood thinners such as warfarin.
- Phenytoin, used to treat epilepsy (fits).
- Medicines used to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas) and repaglinide.
- Rifampicin, an antibiotic.
- 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 certain cancers or certain diseases affecting your immune system.
- Folic acid.
- Contraceptive medicines.

Septrin with food and drink

You should take Septrin 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 Septrin.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Effects on the ability to drive and operate machinery in patients taking this medicine have not been studied.

3. HOW TO TAKE SEPTRIN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Usual Dose

Adults and children over 12 years

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

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

Special Dose

The dose of Septrin 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 Septrin 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 Septrin.
- Take blood to test whether the medicine is working properly.

If you take Septrin 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 Septrin.

If you take more Septrin than you should

If you take more Septrin 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 Septrin you may:

- Feel or be sick.
- Feel dizzy or confused.

If you forget to take Septrin

- 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 Septrin can cause side effects, although not everybody gets them. You may experience the following side effects with this medicine.

Stop taking Septrin 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)

- A fungal infection called thrush or candidiasis which can affect your mouth or vagina
- 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 Warnings and precautions)
- 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 (stools)
- 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
- Loss of appetite

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SEPTRIN

- Keep out of the sight and reach of children.
- Do not store above 25°C. Protect from light.
- Do not take the tablets after the expiry date shown on the carton. The expiry date refers to the last day of that month.
- Store in the original package with this leaflet.
- If the tablets become discoloured or show signs of any other deterioration, you should seek the advice of your pharmacist who will advise you what to do.
- 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Septrin contains

Septrin is made up of two different medicines called sulfamethoxazole and trimethoprim. These medicines are sometimes given the combined name co-trimoxazole.

Each tablet contains 160mg of trimethoprim and 800mg of sulfamethoxazole.

The other ingredients of Septrin are: povidone, sodium starch glycollate (Type A), magnesium stearate and docusate sodium.

What Septrin looks like and contents of the pack

Septrin is a white, elongated tablet marked "GX 02C" on one side and a scoreline on the other side.

Septrin is available in the blister packs of 10, 20, 30 and 100 tablets.

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POM

Septrin is manufactured by Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.

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