

PACKAGE LEAFLET

Package Leaflet: Information for the User

Septrin 80 mg/400 mg Tablets

Trimethoprim and Sulfamethoxazole

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 80 mg/400 mg Tablets
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 80 mg/400 mg Tablets (called 'Septrin' in this leaflet) is a combination of two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by 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 *Pneumocystis jirovecii* pneumonia) caused by a bacteria called *Pneumocystis jirovecii* (previously known as *Pneumocystis carinii*) (some people call this 'PJP').

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.
- an infection caused by a bacteria called toxoplasma (toxoplasmosis).
- an infection called brucellosis, if other treatments were not effective and in combination with other agents in line with national treatment guidelines.

Septrin tablets are indicated in children (>12 to <18 years old) and adults (>18 years old).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

2. What you need to know before you take Septrin

Do not take Septrin if:

- you are allergic to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of this medicine (listed in section 6).
- 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 severe 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.
- Septrin should not be given to infants during the first 6 weeks of life.

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

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS)) 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. The occurrence of a generalised skin redness with pustules, accompanied by fever, should raise the suspicion of a serious reaction called acute generalised exanthematous pustulosis (AGEP) (see section 4). 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 including fever. 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, but it could take up to 8 weeks after drug administration in cases of DRESS (see section 4).

If you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms 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.

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.

If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.

Talk to your doctor or pharmacist before taking Septrin if:

- you have severe allergies or bronchial asthma.
- you have been told that you are at risk for 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 a disease called glucose 6 phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- 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 or if you take 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. High levels of potassium in your blood, can cause abnormal heart beats (palpitations), nausea, dizziness or headache.

- you have been told by your doctor that you have an abnormally low level of sodium in your blood.
- you have a kidney disease.
- you have been told by your doctor that you have any serious disorders of the blood and blood forming tissues (haematological disorders) e.g. low blood cell counts.

Other medicines and Septrin

Tell your doctor or pharmacist if you are taking, have recently taken or might 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 to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas) and repaglinide.
- 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, such as spironolactone), steroids (like prednisolone) and digoxin.
- Azathioprine, may be used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease.
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting your immune system.
- Folinic acid.
- Rifampicin, an antibiotic.
- 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.

Septrin Tablets contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per dose i.e. that is to say essentially 'sodium free'.

3. How to take Septrin Tablets

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

Standard Dose

Standard dosage recommendations for acute infections

Adults (>18 years old):

STANDARD DOSAGE	
Age	Tablets
>18 years old	Two tablets in a morning and two tablets in an evening

Children over 12 years (>12 to <18 years old)

The schedules for children are according to the child's age and body weight provided in the table below:

Age	Tablets
>12 to <18 years old	Two tablets in a morning and two tablets in an evening
	The dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day

- Septrin should be taken for at least five days.
- Make sure that you finish the course of Septrin which your doctor has prescribed.

Septrin 80 mg/400 mg Tablets are 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 jirovecii* (PPJ).
- treat infections caused by the bacteria toxoplasma (toxoplasmosis) or nocardia (nocardiosis) or brucella (brucellosis).

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 this medicine can cause side effects, although not everybody gets them.

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

- 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.

Call the emergency department immediately if you experience multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this drug as it may be a sign of shock.

If any of the side effects listed below occur, contact your doctor immediately:

- Very rare: Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see Warnings and precautions).
- Unknown frequency: An allergic type reaction in which you may develop flu-like symptoms with fever, rash, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes). These may be symptoms of a condition known as DRESS (Drug reaction with eosinophilia and systemic symptoms) and can be severe and life-threatening (see Warnings and precautions).

You may also experience the following side effects with this medicine.

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.
- Mouth ulcers, cold sores and ulcers or soreness of your tongue.
- Very rare cases of redness generalising to the whole body acute generalised exanthematous pustulosis (AGEP)) (see section 2).
- 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 (low blood cell counts).
- 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.
- Cough.
- Loss of appetite.
- Hypoglycaemia (an abnormally low level of glucose in the blood) Pseudomembranous colitis (Acute inflammation of the small and large intestinal mucosa with formation of pseudomembranous plaques over superficial ulceration).
- Pancreatitis (Acute inflammation of the pancreas).
- Vertigo (An illusion of movement, either of the external world revolving around the individual or of the individual revolving in space).
- Hepatic necrosis (which may be fatal) (breakdown/death of liver tissue).

Unknown frequency (cannot be estimated from the available data)

- Psychotic disorder (a mental state in which you may lose touch with reality).
- Plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Septrin

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the bottle label and carton. The expiry date refers to the last day of that month.

Store in the original package with this leaflet.

Do not throw away any medicines 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 Septrin contains

Septrin is made up of two different active substances called sulfamethoxazole and trimethoprim. Each Septrin 80 mg/400 mg Tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim.

The other ingredients of Septrin 80 mg/400 mg Tablets are povidone, sodium starch glycolate, magnesium stearate and docusate sodium.

What Septrin looks like and contents of the pack

Septrin 80 mg/400 mg Tablets are white, round, biconvex tablets debossed with "S2" on one side and scored on the other side.

Septrin 80 mg/400 mg Tablets are available in blister packs of 50 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Aspen Pharma Trading Limited
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Manufacturer

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Medical Information Enquiries

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