

PACKAGE LEAFLET

Package leaflet: Information for the patient

Septtrin 80 mg/400 mg per ampoule, Concentrate for Solution for Infusion

Trimethoprim and Sulfamethoxazole

Read all of this leaflet carefully before you are given 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 Septtrin is and what it is used for
2. What you need to know before you are given Septtrin
3. How Septtrin is given
4. Possible side effects
5. How to store Septtrin
6. Contents of the pack and other information

1. What Septtrin is and what it is used for

Septtrin 80 mg/400 mg per ampoule, concentrate for solution for infusion (called ‘Septtrin’ 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, Septtrin only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

Septtrin can be used to treat or prevent:

- lung infections (pneumonia) caused by the micro-organism, *Pneumocystis jiroveci* (previously known as *Pneumocystis carinii*) (some people call this ‘PJP’).

Septtrin 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.

Septtrin 80 mg/400 mg per ampoule, concentrate for solution for infusion will usually only be given to you if you are unable to take medicines by mouth.

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

Septtrin for Infusion is indicated in children aged 12 years and under (>6 weeks to <12 years old); children over 12 years old (>12 to < 18 years old) and adults (>18 years old).

2. What you need to know before you are given Septrin

You will not be given Septrin if:

- you are allergic 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 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 Septrin is given.

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 to develop 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, seek immediate 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 disorder called porphyria.
- 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 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.
- You have a kidney disease.

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 used 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.
- Rifampicin, an antibiotic.
- Folinic acid.
- Contraceptive medicines.

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 this medicine is given.

See further in Section 2 under excipients with known effects for more information about ethanol content in the formulation.

Driving and using machines

Effects on the ability to drive and operate machinery in patients taking this medicine have not been studied. See further in Section 2 under excipients with known effects for more information about ethanol and propylene glycol content.

Septin concentrate for solution for infusion contains the following excipients with known effects:

- This medicine contains 38.25 mg sodium (main component of cooking/table salt) in each 5 ml ampoule. This is equivalent to 1.9% of the recommended maximum daily dietary intake of 2 g sodium for an adult.
- This medicine contains sodium metabisulphite (E 223) which may rarely cause severe hypersensitivity reactions and bronchospasm.

- This medicine contains 0.5 mg of alcohol (ethanol) in each 5 ml ampoule which is equivalent to 0.1 mg/ml. The amount in one ampoule of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains 2.25 g propylene glycol in each 5 ml ampoule, which is equivalent to 450 mg/ml. Do not use this medicine in children less than 5 years old; talk to your doctor or pharmacist first, in particular if they use other medicines that contain propylene glycol or alcohol. If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. Propylene glycol in this medicine can have the same effects as drinking alcohol and increase the likelihood of side effects. Use this medicine only if recommended by a doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How Septrin is given

You will never be expected to give yourself this medicine. It will always be given to you by a person who is trained to do so.

Septrin 80 mg/400 mg per ampoule, concentrate for solution for infusion will be given to you as a continuous infusion into your vein. This is where the drug is slowly given to you over a period of time.

Before the medicine is given to you it will be diluted.

The dose you will be given, and the frequency of the dose will depend on:

- The type of infection you have.
- Your weight.
- Your age.

Posology

Standard dosage recommendations for acute infections

Adults (>18 years old):

STANDARD DOSAGE	
Age	Solution for Infusion
>18 years old	2 ampoules (10 ml) every 12 hours

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

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

STANDARD DOSAGE	
Age	Solution for Infusion
>12 to <18 years old	2 ampoules (10 ml) every 12 hours
	The standard dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day, given in two equally divided doses.

Children aged 12 years and under (>6 weeks to <12 years old):

Age	Dosage
6 weeks to 5 months	1.25 ml every 12 hours.
6 months to 5 years	2.5 ml every 12 hours
6 to 12 years	5.0 ml every 12 hours.

	The standard dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day, given in two equally divided doses.
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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 are given more Septrin than you should

If you think you have been given more Septrin, talk to your doctor or nurse straight away.

If you have been given too much Septrin you may:

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

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:

- 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 people)

- 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.
- 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 reach and sight of children.
- Keep the ampoule in the outer carton in order to protect from light.
- Do not store above 30°C.
- Do not have this medicine after the expiry date shown on the carton and label.

6. Contents of the pack and other information

What Septrin contains

- Septrin is made up of two different medicines called sulfamethoxazole and trimethoprim. Each 5 ml ampoule contains 400 mg sulfamethoxazole and 80 mg trimethoprim.
- The other ingredients are : propylene glycol (E1520), trometamol, sodium hydroxide (E524), sodium metabisulphite (E223), ethanol, water for Injections.

What Septrin looks like and contents of the pack

Septrin is a clear faintly yellow to brown solution and is available in 5 ml clear glass ampoules. The ampoules are supplied in packs of 10.

Marketing Authorisation Holder And Manufacturer

Marketing authorisation holder:

Aspen Pharma Trading Limited

3016 Lake Drive

Citywest Business Campus

Dublin 24, Ireland

Manufacturer:

Biologici Italia Laboratories S.r.l

Via Filippo Serpero

2-20060 Masate (Mi), Italy

Medical Information Enquiries

For any Medical Information enquires about this product, please contact:

Tel: 00353 1 630 8400

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