

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Septrin Adult 80 mg/400 mg per 5 ml Oral Suspension**

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

#### **1. What Septrin Adult Suspension is and what it is used for**

Septrin Adult 80 mg/400 mg per 5 ml Oral Suspension (called ‘Septrin Adult Suspension’ 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 Adult Suspension only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

Septrin Adult Suspension can be used to treat or prevent:

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

Septrin Adult Suspension 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

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

Septrin Adult Suspension is indicated in children (>12 to <18 years old) and adults (>18 years old).

#### **2. What you need to know before you take Septrin Adult Suspension**

##### **Do not take Septrin Adult Suspension if:**

- you are allergic to the active substance(s) sulfamethoxazole, trimethoprim, co-trimoxazole or any of the other ingredients of this medicine (listed in section 6).
- If 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 Adult Suspension 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 Adult Suspension.

### **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 Adult Suspension 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 Adult Suspension you must not be re-started on Septrin Adult Suspension at any time. If you develop a rash or these skin symptoms, stop taking Septrin Adult Suspension, 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 Adult Suspension 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 kidney disease.

### **Other medicines and Septrin Adult Suspension**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Septrin Adult Suspension can affect the way some medicines work. Also some other medicines can affect the way Septrin Adult Suspension 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.

### **Septrin Adult Suspension with food and drink**

You should take Septrin Adult Suspension 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 Adult Suspension.

### **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 Adult Suspension contains the following excipients with known effects:**

- 5 g of sucrose per 10 ml dose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.
- 0.03 mg of ethanol in each 5 ml oral suspension which is equivalent to 0.006 mg/ml. The amount in 5ml 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.
- 5 mg of methyl p-hydroxybenzoate (E 218) per 5 ml, which may cause allergic reactions (possibly delayed).
- The vanilla flavour contains sulphur dioxide (E 220) which may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains 6.57 mg sodium (main component of cooking/table salt) in each 5 ml dose. This is equivalent to 0.33% of the recommended maximum daily dietary intake of sodium for an adult.

## **3. How to take Septrin Adult Suspension**

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	Adult Suspension
>18 years old	Two 5 ml spoonfuls in a morning and two 5 ml spoonfuls 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 and provided in the table below:

Age	Adult Suspension
>12 to <18 years old	Two 5 ml spoonfuls in a morning and two 5 ml spoonfuls 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 Adult Suspension should be taken for at least five days.
- Make sure that you finish the course of Septrin Adult Suspension which your doctor has prescribed.
- Septrin Adult Suspension is not usually given to children under 12 years old. If this has been given to your child please speak to your doctor or pharmacist for more information.

## Special dose

The dose of Septrin Adult Suspension 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 Adult Suspension to

- Treat urinary tract (water) infections.
- Treat and prevent lung infections caused by the bacteria *pneumocystis jirovecii* (PJP).
- 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 Adult Suspension.
- Take blood to test whether the medicine is working properly.

## If you take Septrin Adult Suspension 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 Adult Suspension.

## If you take more Septrin Adult Suspension than you should

If you take more Septrin Adult Suspension 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 Adult Suspension you may

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

**If you forget to take Septrin Adult Suspension**

- 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 a forgotten dose.

#### **4. Possible side effects**

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

Stop taking Septrin Adult Suspension 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.

**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.
- Skin lumps or hives (raised, red or white, itchy patches of skin).

- Blisters on your skin or inside your mouth, nose, vagina or bottom.
- Very rare cases of redness generalising to the whole body (acute generalised exanthematous pustulosis (AGEP)) (see section 2).
- 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.
- Inflammation of the eye which causes pain and redness.
- 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)
- An allergic type reaction in which you may develop
- 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:

HPRA Pharmacovigilance.

Website: [www.hpra.ie](http://www.hpra.ie).

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

### **5. How to store Septrin Adult Suspension**

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

- Keep the bottle in the outer carton in order to protect from light.
- Do not store above 25°C.
- Once opened, use within 6 weeks.
- Do not take the suspension after the expiry date shown on the bottle label and carton.
- 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 Adult Suspension contains**

- Septrin Adult Suspension is made up of two different medicines called sulfamethoxazole and trimethoprim. Each 5 ml of Septrin Adult Suspension contains 400 mg sulfamethoxazole and 80 mg trimethoprim.
- The other ingredients of Septrin Adult Suspension are: sucrose, glycerol (E422), dispersible cellulose (E460), carmellose sodium, methyl hydroxybenzoate (E218), saccharin sodium (E954), ammonium glycyrrhizinate, star anise oil, ethanol (alcohol), vanilla flavour containing sulphur dioxide, polysorbate 80 (E433) and purified water.

### **What Septrin Adult Suspension looks like and contents of the pack**

Septrin Adult Suspension is supplied to you in an amber-coloured glass bottle, containing 100 ml of an off-white aniseed flavoured liquid. The medicine comes with a double-ended measuring spoon. One end of the spoon will give you 5 ml of the suspension and the other will give you 2.5 ml.

### **Marketing authorisation holder and manufacturer**

Marketing authorisation holder:  
Aspen Pharma Trading Limited  
3016 Lake Drive  
Citywest Business Campus  
Dublin 24  
Ireland

### **Manufacturer:**

Aspen Bad Oldesloe GmbH  
Industriestrasse 32-36, D-23843 Bad Oldesloe  
Germany

### **Medical information enquiries**

For any Medical Information enquires about this product, please contact:  
Tel: 00353 1 630 8400

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