Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
[Pr] SEPTRA® PEDIATRIC ORAL SUSPENSION
Sulfamethoxazole and trimethoprim oral suspension

This Patient Medication Information is written for the person who will be taking SEPTRA PEDIATRIC ORAL SUSPENSION. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about SEPTRA PEDIATRIC ORAL SUSPENSION, talk to a healthcare professional.

Serious warnings and precautions box

SEPTRA PEDIATRIC ORAL SUSPENSION can cause serious side effects. If you get any of these side effects, stop taking SEPTRA PEDIATRIC ORAL SUSPENSION and get immediate medical help:

- Severe skin reactions that may be life-threatening: These include Steven-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), acute febrile neutrophilic dermatosis (Sweet's syndrome) and acute generalised exanthematous pustulosis (AGEP).
- A liver disease called fulminant hepatic necrosis that may be life-threatening.
- Blood problems including:
    - Agranulocytosis, where the number of white cells in the blood becomes dangerously low.
    - Aplastic anemia, where the bone marrow is unable to make enough blood cells from being damaged.
    - Immune thrombocytopenia, which can be life-threatening.
- Allergic reaction in the lungs and in the airways, where the airways can close up and make breathing difficult, and can be life-threatening if the person does not get medical help.

For further information and symptoms see:
- the "**To help avoid side effects and ensure proper use,…**" section
- the "**What are possible side effects from using SEPTRA PEDIATRIC ORAL SUSPENSION?**" section

What SEPTRA PEDIATRIC ORAL SUSPENSION is used for:

SEPTRA PEDIATRIC ORAL SUSPENSION is used to treat:
- urinary tract infections;
- lung infections such as bronchitis or pneumonia caused by fungus;

- gastrointestinal infections such as cholera or dysentery;
- nocardiosis, an infection of the lungs or other parts of the body;
- brucellosis which is a disease spread from animals to humans. When used to treat brucellosis it is used along with another medicine, gentamicin or rifampicin.

Although you may feel better early in treatment, SEPTRA PEDIATRIC ORAL SUSPENSION should be used exactly as directed. Misuse or overuse of SEPTRA PEDIATRIC ORAL SUSPENSION could lead to the growth of bacteria that will not be killed by SEPTRA PEDIATRIC ORAL SUSPENSION (resistance). This means that SEPTRA PEDIATRIC ORAL SUSPENSION may not work for you in the future.

How SEPTRA PEDIATRIC ORAL SUSPENSION works:
SEPTRA PEDIATRIC ORAL SUSPENSION contains two different antibiotics called sulfamethoxazole and trimethoprim. They work together to kill or to slow or stop the growth of bacteria or fungi that cause disease.

The ingredients in SEPTRA PEDIATRIC ORAL SUSPENSION are:
Medicinal ingredients: trimethoprim and sulfamethoxazole
Non-medicinal ingredients: dispersible cellulose, ethanol (96%), flavour banana, flavour vanilla, glycerol, methyl parahydroxybenzoate, sodium benzoate, sodium carmellose, polysorbate 80, purified water, saccharin sodium and sorbitol solution 70% (non crystallising).

SEPTRA PEDIATRIC ORAL SUSPENSION comes in the following dosage form(s):
Suspension: 40 mg / mL sulfamethoxazole and 8 mg / mL trimethoprim.

Do not use SEPTRA PEDIATRIC ORAL SUSPENSION if:
- you are allergic to sulfamethoxazole, or to trimethoprim;
- you are allergic to any of the other ingredients, in SEPTRA PEDIATRIC ORAL SUSPENSION;
- you have had a condition called thrombocytopenia after receiving trimethoprim or a sulfonamide in the past. Sulfonamides include the diabetes medicines gliclazide and glibenclamide as well as other medicines used to treat a variety of other conditions; you have liver problems;
- you have kidney problems;
- you have blood problems or blood forming problems such as low blood cell counts, including megaloblastic anemia;
- you have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system;
- you are pregnant;
- you are breastfeeding;
- you are taking another medicine called dofetilide, used to treat an irregular heartbeat.

SEPTRA PEDIATRIC ORAL SUSPENSION should not be given to premature babies or to infants less than two months of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SEPTRA PEDIATRIC ORAL SUSPENSION. Talk about any health conditions or problems you may have, including if you:
- have severe allergies or asthma

- don't have enough of the vitamin folate in your body known as a folate deficiency
- are underweight or malnourished
- have a disease called glucose-6-phosphate dehydrogenase deficiency
- are at risk for a rare blood disorder called porphyria, which can affect your skin or nervous system
- have a high level of potassium in your blood
- have a low level of sodium or albumin in your blood
- have heart or lung disease, which may lead to a build-up of fluid in your body
- have hereditary disorder called phenylketonuria and are not on a special diet to help treat your condition
- have hereditary fructose intolerance
- are human immunodeficiency virus (HIV) positive or have a condition called Acquired Immunodeficiency Syndrome (AIDS)

Other warnings you should know about:

Use in Patients with Acquired Immunodeficiency Syndrome (AIDS)
If you have AIDS, you may be more likely to get side effects when receiving SEPTRA PEDIATRIC ORAL SUSPENSION. These may include rash, severe allergic reactions, fever or low blood cell counts, or high liver enzyme blood values. AIDS patients are also more likely to get high potassium or low sodium blood levels after receiving SEPTRA PEDIATRIC ORAL SUSPENSION. AIDS patients who received SEPTRA PEDIATRIC ORAL SUSPENSION have had a serious condition called rhabdomyolysis. In some cases this led to serious kidney problems. See **the Serious side effects and what to do about them** table for symptoms.

Immune thrombocytopenia
SEPTRA PEDIATRIC ORAL SUSPENSION can cause a condition called immune thrombocytopenia which may be life-threatening. In this condition, the immune system attacks platelets in your blood. Symptoms include bruising, a rash on the skin that appears tiny pinpoint-sized reddish or purple spots, usually on the lower legs, bleeding from gums or nose, and blood in urine or blood in the stool. Stop taking SEPTRA PEDIATRIC ORAL SUSPENSION and get immediate medical help if you get any of these symptoms.

Use in patients who have taken sulfamethoxazole-trimethoprim recently such as in the past days to weeks
If you have recently taken the medicines in SEPTRA PEDIATRIC ORAL SUSPENSION, sulfamethoxazole and trimethoprim, you could get serious reactions after receiving SEPTRA PEDIATRIC ORAL SUSPENSION. These include circulatory shock with fever, very low blood pressure and confusion. See **the Serious side effects and what to do about them** table for symptoms.

C. difficile colitis
SEPTRA PEDIATRIC ORAL SUSPENSION may increase your risk of being infected with a bacteria called *C. difficile*. Symptoms include watery diarrhea that happens three or more times per day or diarrhea associated with abdominal cramping.

Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions:

Serious drug interactions with SEPTRA PEDIATRIC ORAL SUSPENSION include:
• medicine used to treat irregular heartbeats, such as dofetilide.

The following may also interact with SEPTRA PEDIATRIC ORAL SUSPENSION:

- spironolactone, used to remove excess water from the body known as a diuretic
- pyrimethamine, used to treat malaria
- zidovudine or lamivudine, used to treat HIV
- warfarin, used to thin the blood
- phenytoin, used to treat epilepsy (fits) and seizures
- azathioprine, used to prevent organ rejection after transplantation
- methotrexate, used to treat cancer or arthritis
- digoxin or procainamide, used to treat heart conditions
- heart and high blood pressure medicines or prednisolone known as a steroid, that can increase the amount of potassium in your blood
- cyclosporine, used after organ transplantation
- amantadine, used to treat Parkinson's disease, multiple sclerosis, the flu or shingles
- glibenclamide, glipizide or tolbutamide (known as sulphonylureas), and repaglinide, used to treat diabetes
- rifampicin, used to treat bacterial infections
- folinic acid, used after cancer treatment or to help with low levels of folate
- contraceptives, used to help prevent pregnancy
- leucovorin, used to treat a type of pneumonia in patients with AIDS

Food Interactions

- Tell your healthcare professional if you or your child have special dietary needs, especially if you are following a potassium rich diet. Potassium rich foods include beans, dark leafy greens, potatoes, squash, yogurt, fish, avocados, mushrooms and bananas.

How to take SEPTRA PEDIATRIC ORAL SUSPENSION:

- Take SEPTRA PEDIATRIC ORAL SUSPENSION exactly as your healthcare professional tells you to.
- You should drink plenty of fluids while taking SEPTRA PEDIATRIC ORAL SUSPENSION. You should also take SEPTRA PEDIATRIC ORAL SUSPENSION along with some food. Ideally, this food would be low in potassium. This is to prevent stomach upset. Talk to your healthcare professional if you have questions about this.
- Follow all instructions given to you by your healthcare professional.
- Shake well before use.

Usual dose:

- Your healthcare professional will decide how much SEPTRA PEDIATRIC ORAL SUSPENSION you or your child will be given.

- The dose you are given and how often you are to take it will depend on:
    - your infection
    - your weight
    - your age

Overdose:
If you have been given too much SEPTRA PEDIATRIC ORAL SUSPENSION you may have the following signs or symptoms:

- loss of appetite
- severe abdominal pain
- nausea and vomiting
- dizziness, drowsiness or confusion
- fainting
- headache
- fever
- blood in urine
- cloudy urine
- yellowing of the skin or whites of the eye
- feeling depressed
- loss of consciousness

If you think you, or a person you are caring for, have taken too much SEPTRA PEDIATRIC ORAL SUSPENSION, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:
Your healthcare professional will prescribe this medicine to you. If you miss a dose talk to your healthcare professional as soon as possible.

Possible side effects from using SEPTRA PEDIATRIC ORAL SUSPENSION:

These are not all the possible side affects you or your child may feel when taking SEPTRA PEDIATRIC ORAL SUSPENSION. If your child experiences any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Feeling weak or tired
- Trouble sleeping
- Vision problems
- Hair loss
- Nose bleed
- Inflammation at the site of injection
- Swelling of body tissues with fluid
- Chills
- Sensitivity to sunlight

- Palpitations (heart beat that feels too fast, strong or irregular
- Cold sores, ulcers, or soreness of your tongue or inside of your mouth
- Dry mouth
- Heartburn
- Abdominal pain or gas
- Constipation
- Nausea, vomiting and diarrhea
- Loss of appetite
- Passing more or less urine than usual; difficulty reaching bathroom in time
- Muscle and joint pain or muscle weakness
- Tingling or numbness in your hands and feet
- Problems controlling your movements
- Uncontrollable shaking
- Vertigo (sensation of movement or feeling off balance)
- Ringing or other unusual sounds in your ears
- Headache
- Inflammation of your eye that causes pain and redness
- Depression
- Apathy (indifference and a lack of motivation)
- Feeling unsteady or dizzy
- Loss of appetite
- Tooth and/or tongue discoloration

SEPTRA PEDIATRIC ORAL SUSPENSION can cause abnormal blood test results.

Serious side effects and what to do about them

Frequency/Side Effects/Symptom	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Allergic reactions: swelling of face, mouth, tongue or throat which may be red and painful and/or cause difficulty in swallowing, red patches on the skin, rash, hives, fever (high temperature), joint pain, feeling sick (nausea), being sick (vomiting), chest pain.			**√**

Stevens-Johnson syndrome (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands.			**√**
Toxic Epidermal Necrolysis (severe skin reaction): redness, blistering and/or peeling of large areas of the skin.			**√**
Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reaction that may affect more than one organ): fever, severe skin rash, peeling skin, and abnormal blood and liver function tests.			**√**
Acute febrile neutrophilic dermatosis (Sweet's syndrome) (a serious skin condition): plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever.			**√**
Acute generalised exanthematous pustulosis (AGEP) (serious skin condition): very rare cases of redness generalising to the whole body.			**√**
Respiratory toxicity, Fulminant lung injury, Acute Respiratory Distress Syndrome (ARDS) (Lung problems sometimes progressing to severe rapid irreversible lung tissue damage): Difficulty breathing, cough, wheezing, shortness of breath, tightness of the chest. **This can be serious and lead to death.**			**√**
Hypersensitivity reactions of the respiratory tract (allergic reaction in the lungs and airways, where the airways can close up and make breathing difficult): shortness of breath, cough, wheezing, and chest tightness.			**√**

Aseptic meningitis (inflammation of the protective lining of the brain that is not caused by infection): including sudden headache or stiffness of your neck, accompanied by fever, nausea, vomiting, sensitivity to light.			**√**
Acute inflammation of the small and large intestine *Pseudomembranous colitis*: including watery or bloody diarrhea, abdominal cramps, pain or tenderness, fever, nausea, dehydration.			**√**
Fits (convulsions or seizures)			**√**
Heart problems: Increased heart rate, chest pain, shortness of breath.			**√**
Pancreatitis (Acute inflammation of the pancreas): including upper abdominal pain that spreads to the back, swollen and tender abdomen, nausea, vomiting, fever.			**√**
Hypoglycaemia (an abnormally low level of sugar in the blood): including dizziness or light-headedness, shakiness, nervousness or anxiety, feeling confused, sweating, chills.			**√**
Problems with your urine: pain or difficulty passing urine, blood or cloudiness in your urine.			**√**
Hepatitis (inflammation of the liver): fatigue, fever, body ache, abdominal pain, dark urine or pale stools, difficulty to urinate.			**√**
Jaundice (yellowing of the skin and whites of the eyes).			**√**
An infection called thrush or candidiasis which can affect your mouth or vagina.			**√**
Hallucinations: seeing, hearing, smelling, tasting or feeling things that don't exist outside your mind.			**√**
Immune thrombocytopenia			**√**

(dangerously low number of platelets in the blood due to immune system attacking the platelets): bruising, a rash on the skin that appears tiny pinpoint-sized reddish or purple spots, usually on the lower legs, bleeding from the gums or nose, and blood in the urine or stool.			
Haemophagocytic lymphohistiocytosis (condition where your white blood cells attack your organs and other blood cells): fever, enlarged liver and spleen, swollen lymph nodes, skin rashes, yellowing of your skin and eyes, breathing problems, stomach-ache, vomiting and diarrhea, headache, trouble walking, feeling weak and bruising easily. **This can be serious and lead to death.**			√
Aplastic anemia: feeling tired, feeling short of breath, pale skin, unexplained or easy bruising, fever, chills, sore throat, and a general feeling of being unwell.			√
Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs): • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • swelling and redness of eyes or face • flu-like feeling, fever, chills, body aches, swollen glands, cough • shortness of breath, chest pain or discomfort			√
Angioedema: swelling of the face, hands, feet, genitals, tongue or throat, difficulty swallowing or			√

breathing; swelling of the digestive tract which may cause diarrhea, nausea or vomiting			
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center; possibly swollen lips, mild itching or burning			√
Circulatory shock (condition where the body doesn't get enough blood flow): fever, very low blood pressure and confusion.			√
C. difficile colitis (being infected with a bacteria called C. difficile): watery diarrhea that happens three or more times per day or diarrhea with stomach pain.			√
Fulminant hepatic necrosis (life threatening condition with rapid death of liver cells): yellowing of the skin or the white of the eyes, pain in the upper right side of the stomach, abdominal distension, nausea, vomiting.			√
Rhabdomyolysis (serious muscle breakdown): muscle spasms, weakness, red-brown (tea-coloured) urine.			√
Agranulocytosis (a condition where a type of white blood cell becomes dangerously low): fever, chills, sore throat, mouth pain, weakness, tiredness, fast heart rate, fast breathing.			√

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store SEPTRA PEDIATRIC ORAL SUSPENSION between 15° and 30°C. Protect from light.
Keep out of reach and sight of children.

If you want more information about SEPTRA PEDIATRIC ORAL SUSPENSION:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.aspenpharma.ca), or by calling 1-844-330-1213.

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