

SCHEDULING STATUS

S4

CO-TRIMOXAZOLE DS PHARMC, 160 mg/800 mg, tablets

CO-TRIMOXAZOLE PHARMC, 80 mg/400 mg, tablets

CO-TRIMOXAZOLE PAED PHARMC, 40 mg/200 mg, suspension

Trimethoprim and sulfamethoxazole

CO-TRIMOXAZOLE DS PHARMC is sugar free

CO-TRIMOXAZOLE PHARMC is sugar free

CO-TRIMOXAZOLE PAED PHARMC contains:

Sugar as sucrose 2 500 mg/5 mL

Sweetener as Sodium Saccharin 20 mg/5 mL

Read all of this leaflet carefully before you start taking CO-TRIMOXAZOLE PHARMC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CO-TRIMOXAZOLE PHARMC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What CO-TRIMOXAZOLE PHARMC is and what it is used for

CO-TRIMOXAZOLE DS PHARMC, CO-TRIMOXAZOLE PHARMC and CO-TRIMOXAZOLE PAED PHARMC (called CO-TRIMOXAZOLE PHARMC in this leaflet) contains two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain bacteria. As CO-TRIMOXAZOLE PHARMC only works against some types of bacteria, it is only suitable for treating some types of infections.

It is used for:

1. Upper and lower lung infections
2. Urinary bladder or urinary tract infections
3. Gastrointestinal tract (your mouth, oesophagus (gullet), stomach and intestines) infections
4. Genital tract (reproductive track including sexually transferred diseases) infections
5. Skin infections
6. Other infections caused by bacteria that CO-TRIMOXAZOLE PHARMC works against.

CO-TRIMOXAZOLE DS PHARMC and CO-TRIMOXAZOLE PHARMC can be used in children (from 12 to 18 years old) and adults (from 18 years old).

CO-TRIMOXAZOLE PAED PHARMC can be used in adults that cannot swallow and in infants (from 6 weeks to 2 years old) and children (from 2 to 12 years old).

2. What you need to know before you take/give CO-TRIMOXAZOLE PHARMC**Do not take/give CO-TRIMOXAZOLE PHARMC**

- If you/your child are hypersensitive (allergic) to sulfamethoxazole, trimethoprim, sulfonamides or any of the other ingredients of CO-TRIMOXAZOLE PHARMC (listed in section 6).
- If you/your child have been told that you have porphyria
- If you/your child have severe liver or severe kidney problems.
- If you/your child have been told that you have an anaemia due to not having enough folic acid.
- If you are pregnant or breastfeeding.
- CO-TRIMOXAZOLE PAED PHARMC should not be given to infants during the first 6 weeks of life.

Warnings and precautions

Take special care with CO-TRIMOXAZOLE PHARMC

- If you/your child are suffering from AIDS or are having special treatment that lowers your immune system, e.g. after an organ transplant. You can experience more severe side-effects.
- If you/your child have skin rashes, often accompanied by flu-like symptoms after taking CO-TRIMOXAZOLE PHARMC. The rash may progress to widespread blistering or peeling of the skin. This can be a serious skin reaction to CO-TRIMOXAZOLE PHARMC. Stop taking CO-TRIMOXAZOLE PHARMC and seek urgent advice from your doctor.
- If you/your child 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. Your doctor might prescribe additional folic acid with your CO-TRIMOXAZOLE PHARMC treatment.

- If you are elderly you may have more severe side effects, e.g. problem with your blood causing bruises or bleeding (thrombocytopenia). This can happen more frequently if you are also taking water tablets, e.g. thiazides.
- When you/your child's treatment is over a long period, your doctor may monitor your blood more regularly.
- If you/your child have kidney problems, your doctor might reduce the CO-TRIMOXAZOLE PHARMC dosage (see section 3). You/your child should take enough fluids , especially if you are on high dosages of CO-TRIMOXAZOLE PHARMC.
- If you/your child are allergic to sulfonamides. Examples include sulfonylurea (such as gliclazide and glibenclamide) or acetazolamide and thiazide diuretics (water tablets). You might be allergic to CO-TRIMOXAZOLE PHARMC as well.

Other medicines and CO-TRIMOXAZOLE PHARMC

Always tell your healthcare provider if you/your child are taking any other medicine.(This includes complementary or traditional medicines.)

- If you/your child are taking any of the following, as the effect of these medicines can become stronger and your doctor might monitor you more closely:
 - Warfarin or other medicines to thin your blood
 - Methotrexate, used to treat certain cancers or certain diseases affecting your immune system.
 - Phenytoin, used to treat epilepsy
- Sulfonylurea compounds, used to treat diabetes, can become stronger when using CO-TRIMOXAZOLE PHARMC.
- Para-aminobenzoic acid (PABA) is a supplement and can increase your risk of side effects, e.g. crystals forming in your urine.
- CO-TRIMOXAZOLE PHARMC can change the results of some laboratory tests.

- If you/your child are taking any of the following, as the effect of these medicines can become stronger and your doctor might change your treatment:
 - Digoxin or procainamide to treat problems with the way your heart beats
 - Tolbutamide and repaglinide used to treat diabetes.
- Cyclosporin, used in e.g., kidney transplant, as it can cause your kidneys to work less effective.
- Pyrimethamine used to treat and prevent malaria, and to treat diarrhoea, as you can develop side effects, e.g., anaemia.
- Zidovudine used in the treatment of HIV, as it can increase your risk of develop less blood cells.
- Lamivudine used in the treatment of HIV, as CO-TRIMOXAZOLE PHARMC at high dosages can increase the effect of lamivudine.
- Medicines that can increase the amount of potassium in your/your child's blood, such as diuretics (water tablets, which help increase the amount of urine you produce, such as spironolactone), steroids (like prednisolone) and digoxin or ACE inhibitors (may be used to treat high blood pressure or some heart problems). These medicines can increase the amount of potassium to dangerously high levels in your blood.
- Folinic acid, a supplement can lower the effect of CO-TRIMOXAZOLE PHARMC
- Contraceptives can become less effective when taking with CO-TRIMOXAZOLE PHARMC. You should use additional protection while on CO-TRIMOXAZOLE PHARMC treatment.
- Azathioprine used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease. Your doctor might monitor your blood cells more closely.

CO-TRIMOXAZOLE PHARMC with food and drink

The tablets should be swallowed with a glass of water and food. The suspension should be given by mouth after food.

Drink plenty of fluid such as water while you are taking CO-TRIMOXAZOLE PHARMC.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking CO-TRIMOXAZOLE PHARMC. You should not take CO-TRIMOXAZOLE PHARMC while you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent CO-TRIMOXAZOLE PHARMC may interfere with your/your child's daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which CO-TRIMOXAZOLE PHARMC affects you/your child.

CO-TRIMOXAZOLE PHARMC contains Nipastat

CO-TRIMOXAZOLE PHARMC contains Nipastat, a mixture of parahydroxybenzoate esters. It may cause allergic reactions (possibly delayed).

CO-TRIMOXAZOLE PAED PHARMC contains alcohol and sucrose

CO-TRIMOXAZOLE PAED PHARMC contains alcohol 0,025 mg of alcohol (ethanol) in each 5 mL which is equivalent to 0,5 % v/v alcohol(ethanol). The amount in 5 mL of this medicine is equivalent to 0,5 mL of beer and less than 0,5 mL of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

CO-TRIMOXAZOLE PAED PHARMC contains 2 500 mg per 5 mL sucrose. This should be taken into account if you/your child have diabetes mellitus.

If you have been told by your doctor that you/your child have an intolerance to some sugars, contact your doctor before taking or giving this CO-TRIMOXAZOLE PAED PHARMC.

3. How to take/give CO-TRIMOXAZOLE PHARMC

Do not share medicines prescribed for you with any other person.

Always take CO-TRIMOXAZOLE PHARMC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dosage and length of CO-TRIMOXAZOLE PHARMC treatment will depend on your needs and the infection being treated.

Adults and children over 12 years

CO-TRIMOXAZOLE DS PHARMC

The usual dose is one CO-TRIMOXAZOLE DS PHARMC tablet every 12 hours after meals. The maximum dose (for particularly severe cases) is one and a half CO-TRIMOXAZOLE DS PHARMC tablets every 12 hours. The minimum dosage for long term treatment (more than 14 days) is half a CO-TRIMOXAZOLE DS PHARMC tablet every 12 hours.

CO-TRIMOXAZOLE PHARMC

The usual dose is two CO-TRIMOXAZOLE PHARMC tablets every 12 hours after meals. The maximum dose (for particularly severe cases) is three CO-TRIMOXAZOLE PHARMC tablets every 12 hours. The minimum dosage for long term treatment is one CO-TRIMOXAZOLE PHARMC tablet every 12 hours.

Infants and children

CO-TRIMOXAZOLE PAED PHARMC (Shake the bottle before use)

6 weeks to 5 months: Half (2,5 mL) a medicine measure twice daily.

6 months to 5 years: One (5 mL) medicine measure twice daily.

6 years to 12 years: Two (10 mL) medicine measures twice daily.

Renal Impairment

Your doctor will do a blood test and calculate your dosage depending on the results.

No Information is available for children with renal failure.

Your doctor will tell you how long your treatment with CO-TRIMOXAZOLE PHARMC will last.

Do not stop treatment early because the infection can start again. If you have the impression that the effect of CO-TRIMOXAZOLE PHARMC is too strong or too weak, tell your doctor or pharmacist.

If you/your child take more CO-TRIMOXAZOLE PHARMC than you/they should

When taken more CO-TRIMOXAZOLE PHARMC than you/they should, you/your child may feel nausea, vomit, dizzy and confused. In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take/give a dose of CO-TRIMOXAZOLE PHARMC

If you forget to take/give a dose, take/give it as soon as you remember it. Do not take/give a double dose to make up for the forgotten dose.

4. Possible side effects

CO-TRIMOXAZOLE PHARMC can have side effects.

Not all side effects reported for CO-TRIMOXAZOLE PHARMC are included in this leaflet. Should your/your child's general health worsen or if you/your child experience any untoward effects while taking CO-TRIMOXAZOLE PHARMC, please consult your health care provider for advice.

If any of the following happens, stop taking/giving CO-TRIMOXAZOLE PHARMC and tell your doctor immediately or go to the casualty department at your nearest hospital

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, chest pain, red patches on the skin. This can be an allergic reaction to CO-TRIMOXAZOLE PHARMC.
- Severe blistering of the skin, starting with reddish spots. These serious skin reactions includes toxic epidermal necrolysis (Lyell's syndrome), Steven-Johnson syndrome (SJS), fixed drug eruption to name a few (see also section 2).
- At the start of treatment, the occurrence of a generalised skin redness with pustules, accompanied by flu-like symptoms, e.g. fever, should raise the suspicion of a serious reaction called acute generalised exanthematous pustulosis (AGEP) (see also section 2).
- Unexpected worsening of cough and shortness of breath.
- Excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations, which can be life-threatening if not diagnosed and treated early. If you/your child 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.
- Increase in liver enzymes (blood tests) and inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

- Sudden headache or stiffness of your neck, accompanied by fever. This can be Meningitis aseptic.

These are all very serious side effects. If you/your child have them, you may have had a serious reaction to CO-TRIMOXAZOLE PHARMC. You/your child may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following

Frequent side effects

- A fungal infection called thrush or candidiasis which can affect the mouth or vagina
- High levels of potassium in your blood, which can cause abnormal heart beats (palpitations).
- Headache
- Nausea
- Diarrhoea
- Rash

Less frequent side effects

- Pseudomembranous colitis (infection of the colon resulting in watery and sometimes bloody stools)
- Changes in the blood cells, resulting in feeling weak, tired or listless, pale skin, and more frequent infections
- Hypothyroidism where the thyroid doesn't create and release enough thyroid hormone into your bloodstream. This makes you feel tired, gain weight and unable to tolerate cold temperatures.
- Low blood sugar
- Low sodium concentration in your blood

- Decreased appetite
- Build-up of acid in your body (metabolic acidosis)
- Depression
- Seeing strange or unusual sights (hallucination)
- Psychotic disorder (a mental state in which you may lose touch with reality)
- Loss of balance and coordination (ataxia)
- Dizziness
- Feeling tired
- Difficulty to sleep
- Tingling or numbness in your hands and feet
- Seizures
- Vision disorders, seeing flickering or flashing lights
- Short-sighted for a short period
- Inflammation of the eye which causes pain and redness
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears
- Cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes)
- Vomiting
- Swollen and inflamed tongue
- Inflamed and sore mouth
- Inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (Pancreatitis)
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Arthralgia (pains in the joints)
- Myalgia (pains in the muscles)

- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual.
- Blood or cloudiness in your urine
- Kidney problems

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you/your child get 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 to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of CO-TRIMOXAZOLE PHARMC

5. How to store CO-TRIMOXAZOLE PHARMC

Store all medicines out of reach of children.

- Store at or below 25 °C
- Protect from light and moisture.
- Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What CO-TRIMOXAZOLE PHARMC contains

The active substances are trimethoprim and sulfamethoxazole.

CO-TRIMOXAZOLE DS PHARMC

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

The other ingredients of are hydrogenated vegetable oil; magnesium stearate; microcrystalline cellulose; Nipastat; starch, maize; Starch, pregelatinised; starch, sodium glycolate.

CO-TRIMOXAZOLE PHARMC

Each tablet contains 80 mg trimethoprim and 400 mg sulfamethoxazole.

The other ingredients of are hydrogenated vegetable oil; magnesium stearate; microcrystalline cellulose; Nipastat; starch, maize; Starch, pregelatinised; starch, sodium glycolate.

CO-TRIMOXAZOLE PAED PHARMC

Each 5 mL suspension contains 40 mg trimethoprim and 200 mg sulfamethoxazole.

The other ingredients of are aluminium magnesium silicate, aniseed oil, ethanol, Nipastat, Polysorbate 80, purified water, sodium carboxymethylcellulose, sodium citrate, sodium saccharin, sucrose.

What CO-TRIMOXAZOLE PHARMC looks like and contents of the pack

CO-TRIMOXAZOLE DS PHARMC, tablets

White, capsule-shaped, biconvex, bisected tablets.

The tablet can be divided into equal halves.

Packs containing 10 tablets in blister packs, 30 or 100 tablets in securitainers.

CO-TRIMOXAZOLE PHARMC, tablets

White, flat, bisected bevelled edged tablets.

The tablet can be divided into equal halves.

Packs containing 20 or 100 tablets in securitainers or 500 in amber PVC bottles.

CO-TRIMOXAZOLE PAED PHARMC, suspension

A smooth, white suspension with a characteristic aniseed odour.

Bottles of 50 mL or 100 mL.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pharmacorp (Pty) Ltd

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RSA

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CO-TRIMOXAZOLE PAED PHARMC Y/20.2.1/146

Access to the corresponding Professional Information

Can be accessed on SAHPRA website: <https://pi-pil-repository.sahpra.org.za>