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 per 5 mL, 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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2. What you need to know before you take CO-TRIMOXAZOLE PHARMC

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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 CO-TRIMOXAZOLE PHARMC

Do not take CO-TRIMOXAZOLE PHARMC

- If you are hypersensitive (allergic) to sulfamethoxazole, trimethoprim, sulfonamides or any of the other ingredients of CO-TRIMOXAZOLE PHARMC (listed in section 6).
- If you have been told that you have porphyria
- If you have severe liver or severe kidney problems.
- If you 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 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 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 develop several symptoms at the same time, or close together, such as fever, swollen glands, unusual tiredness or weakness, dizziness, shortness of breath, easy bruising, or a skin rash, stop taking CO-TRIMOXAZOLE PHARMC and contact your doctor immediately. These symptoms may be a sign of a rare but serious condition called hemophagocytic lymphohistiocytosis (HLH), where the body's immune system becomes overactive and causes severe inflammation. Early diagnosis and treatment are important because this condition can become life-threatening if it is not treated promptly.
- If 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. 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 your treatment is over a long period, your doctor may monitor your blood more regularly.
- If you have kidney problems, your doctor might reduce the CO-TRIMOXAZOLE PHARMC dosage (see section 3). You should take enough fluids, especially if you are on high dosages of CO-TRIMOXAZOLE PHARMC.
- If you 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 health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you 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 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 developing 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 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.

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 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.

CO-TRIMOXAZOLE PHARMC contains Nipastat (parahydroxybenzoate esters), alcohol and sucrose

Nipastat: It is a mixture of parahydroxybenzoate esters. It may cause allergic reactions (possibly delayed).

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

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

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

3. How to take 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

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

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

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

How and when to take CO-TRIMOXAZOLE PHARMC

The tablets should be swallowed with a glass of water and taken after food.

The suspension should be given by mouth after food. Shake the bottle before use.

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

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 take more CO-TRIMOXAZOLE PHARMC than you should

When taken more CO-TRIMOXAZOLE PHARMC than you/they should, you 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 a dose of CO-TRIMOXAZOLE PHARMC

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

CO-TRIMOXAZOLE PHARMC can have side effects.

Not all side effects reported for CO-TRIMOXAZOLE PHARMC are included in this leaflet. Should your general health worsen or if you 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 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 include 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.
- Several symptoms at the same time, or one after another over a short period, such as fever, swollen glands, feeling weak, dizziness, shortness of breath, bruising, or a skin rash, contact your doctor immediately. These may be signs of a rare but serious condition called hemophagocytic lymphohistiocytosis (HLH), in which the immune system becomes overactive and causes inflammation throughout the body. Early diagnosis and treatment are important because this condition can be life-threatening.
- 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 have them, you may have had a serious reaction to CO-TRIMOXAZOLE PHARMC. You 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
- Sort-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 tong
- 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 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who- umc.org) found on the SAHPRA website.

In addition, side effects can also be reported to info@pharmacorp.co.za.

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, maize starch, pregelatinised starch, 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, maize starch, pregelatinised starch, 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 DS PHARMC	Y/20.2.1/144
CO-TRIMOXAZOLE PHARMC	Y/20.2.1/145
CO-TRIMOXAZOLE PAED PHARMC	Y/20.2.1/146

Access to the corresponding Professional Information

(and the translated Patient Information Leaflet)

www.pharmacorp.co.za