

Biotech Laboratories (Pty) Ltd

Co-Trimoxazole 480 Biotech (P/20.2.1/260)

Co-Trimoxazole 960 Biotech (W/20.2.1/88)

Each tablet contains 400 mg sulphamethoxazole and 80 mg trimethoprim

Each tablet contains 800 mg sulphamethoxazole and 160 mg trimethoprim

Module 1.5.5.4 Proposed Clean PIL

Type IA_{IN} – PI & PIL update as per PV response

Submitted: 22 August 2023

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CO-TRIMOXAZOLE 480 BIOTECH Tablets

CO-TRIMOXAZOLE 960 BIOTECH Tablets

Trimethoprim and Sulphamethoxazole

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CO-TRIMOXAZOLE BIOTECH 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

1. What CO-TRIMOXAZOLE BIOTECH is and what it is used for
2. What you need to know before you take CO-TRIMOXAZOLE BIOTECH
3. How to take CO-TRIMOXAZOLE BIOTECH
4. Possible side effects
5. How to store CO-TRIMOXAZOLE BIOTECH
6. Contents of the pack and other information

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

CO-TRIMOXAZOLE BIOTECH contains sulphonamide and trimethoprim, a combination which is used to

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prevent and treat infections.

CO-TRIMOXAZOLE BIOTECH can be used for the treatment of the following infections:

Urinary tract infections

Genital infections

Respiratory tract infections

These tablets may also be used for other conditions as determined by your doctor or healthcare professional.

This medicine will not work for colds, flu or other virus infections

2. What you need to know before you take CO-TRIMOXAZOLE BIOTECH:**Do not take CO-TRIMOXAZOLE BIOTECH:**

- If you are hypersensitive (allergic) to sulphonamides or trimethoprim or any of the other ingredients of CO-TRIMOXAZOLE BIOTECH (listed in section 6).
- If you suffer from a condition called porphyria (a group of disorders caused by an over-accumulation of porphyrin which helps haemoglobin, the protein that carries oxygen in the blood)
- If your liver function is impaired, or you have liver damage
- If you have a liver disease such as jaundice (a condition in which there is yellowing of the whites of the eyes, skin, and mucous membranes, caused by bile pigments in the blood).
- If you are pregnant or breastfeeding your baby.
- If you have anaemia (lack of red blood cells or dysfunctional red blood cells in the body) with megaloblast in the bone marrow (megaloblastic anaemia).
- If you have anaemia (lack of red blood cells or dysfunctional red blood cells in the body) due to folic acid (type of B vitamin) deficiency
- If you have impaired kidney function
- If you use medication for seizures (anticonvulsant medication).

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CO-TRIMOXAZOLE BIOTECH should not be given to premature or new-born infants within 1 to 2 months of birth.

Warnings and precautions

Take special care with CO-TRIMOXAZOLE BIOTECH:

- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and medicine reaction with eosinophilia and systemic symptoms) have been reported with the use of CO-TRIMOXAZOLE BIOTECH appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Treatment should be stopped and not re-started if you develop any of the above reactions.
- CO-TRIMOXAZOLE BIOTECH may cause an allergic skin reaction causing skin lesions such as a red, itchy patch or big, fluid-filled blisters in the same spot on your skin every time you're exposed to that medicine (fixed drug eruption).
- CO-TRIMOXAZOLE BIOTECH (sulphonamide and trimethoprim combinations) may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight, even for brief periods of time, may cause severe sunburn. When you begin taking this CO-TRIMOXAZOLE BIOTECH:
 - Stay out of direct sunlight, especially between the hours of 10:00 am and 15:00 pm, if possible.
 - Wear protective clothing, including hat and sunglasses
 - Apply a sun block product that has a skin protection factor (SPF) of at least 15.
 - Do not use a sunlamp or tanning bed or both.
- If you have a weak immune system (such as those suffering from acquired immunodeficiency syndrome (AIDS) or patients receiving immunosuppressive therapy) and taking CO-TRIMOXAZOLE BIOTECH you may experience more side-effects such as a skin rash, fever, and blood disorders (characterised by more frequent infections, bruising, nosebleeds, or bleeding gums).

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- If you are elderly (elderly patients are more likely to suffer from serious side effects)
 - If your kidneys are not fully functional; it may be necessary to reduce the dose of CO-TRIMOXAZOLE BIOTECH.
 - If you are taking medicine called “pyrimethamine” with CO-TRIMOXAZOLE BIOTECH, you may develop immature red blood cells which will cause you to feel weak and have a lack of energy.
 - If you suffer from a condition called G6PD deficiency
 - If you suffer from asthma
 - If you have an electrolyte imbalance such as too much potassium or low sodium levels.
 - If the chemical balance of the acids and bases in your body is disrupted (metabolic acidosis).

Women on oral contraceptives (birth control tablets) should temporarily use a barrier method in addition to the pill while on CO-TRIMOXAZOLE BIOTECH treatment.

Ensure that you drink enough fluids to prevent kidney stones.

Regular blood tests should be done if you take for CO-TRIMOXAZOLE BIOTECH for long periods. This is to detect early indications of serious blood disorders and to detect a folate deficiency.

If you develop symptoms such as coughing, fever or difficulty breathing (Acute Respiratory Distress Syndrome), CO-TRIMOXAZOLE BIOTECH treatment should be stopped.

A life-threatening disorder Haemophagocytic lymphohistiocytosis (HLH) characterised by symptoms of systemic pain and swelling (swelling of the liver and spleen, high level of a certain type of fat (triglycerides) in the blood, one or more of your blood cell types is lower than it should be) can occur. CO-TRIMOXAZOLE BIOTECH treatment should be stopped if this syndrome is diagnosed by your doctor.

Other medicine and CO-TRIMOXAZOLE BIOTECH

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

- Warfarin (medicine that prevent your blood from forming clots)
- Methotrexate (medicine used to suppress the immune system for e.g., during treatment of rheumatoid arthritis, lupus or Chron's disease)
- Ciclosporin and azathioprine (immune suppressant used in organ and tissue transplants, rheumatoid arthritis, certain skin conditions)
- Diuretics (water pills)
- Digoxin (medicine to treat heart failure or irregular heartbeat)
- Lamivudine zidovudine or zalcitabine (medicine to treat HIV infections)
- ACE inhibitors (medicine for high blood pressure for e.g., enalapril)
- Pyrimethamine (medicine to treat parasite diseases)
- Antidiabetic medicine belonging to the sulphonyl (e.g., glimepride, glibenclamide, gliclazide, tolbutamide); as well as repaglinide.
- Phenytoin (medicine to treat convulsions)
- Phenylbutazone (anti-inflammatory) or sulpinpyrazone (used treatment of gout).
- Methenamine (used for urinary tract infections)
- Rifampicin (used in treatment of tuberculosis)
- Procainamide (heart medicine), amantadine (treatment of Parkinson's disease)
- Folinic acid supplements
- Oral contraceptives (see Warnings and precautions above).

CO-TRIMOXAZOLE BIOTECH with food or drink:

CO-TRIMOXAZOLE BIOTECH is best taken with a full glass of water after meals. Several additional

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glasses of water should be taken every day, unless otherwise directed by your doctor. Drinking extra water will help to prevent some unwanted side-effects.

You must take these tablets after meals morning and evening.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Do not use CO-TRIMOXAZOLE BIOTECH if you are pregnant. Sulphonamides and trimethoprim pass into the breast milk. Mothers who are taking this medicine and who wish to breastfeed should discuss this with their doctor.

Driving and using machines

It is not always possible to predict to what extent CO-TRIMOXAZOLE BIOTECH may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which CO-TRIMOXAZOLE BIOTECH affects you.

CO-TRIMOXAZOLE BIOTECH may cause some people to become dizzy, drowsy or have headaches. Caution is advised when driving or operating machinery.

3. How to take CO-TRIMOXAZOLE BIOTECH

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

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

Your doctor will tell you how long your treatment with CO-TRIMOXAZOLE BIOTECH will last. Do not

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stop treatment early because your symptoms may return. If you have the impression that the effect of CO-TRIMOXAZOLE BIOTECH is too strong or too weak, tell your doctor or pharmacist.

The quantity of CO-TRIMOXAZOLE BIOTECH that you need to take, and the duration of your treatment will be determined by your doctor or healthcare professional according to your specific needs and condition.

Take these tablets after meals.

To help clear up your infection completely, keep taking this medicine for the full period of the treatment, even if you begin to feel better after a few days.

This medicine works best when there is a constant amount in the blood and urine. To help keep the amount constant, do not miss any doses. It is best to take the doses at evenly spaced times day and night.

The dose will be different for different patients. If your dose is different, do not change it unless your doctor or healthcare professional tells you.

The length of your treatment will depend on the severity or type of infection.

The usual dose is:

Children 6 to 12 years: One CO-TRIMOXAZOLE 480 BIOTECH tablet every 12 hours after meals.

Adults and children over 12 years: Two CO-TRIMOXAZOLE 480 BIOTECH (or one CO-TRIMOXAZOLE 960 BIOTECH) twice daily, morning and evening after meals.

Your doctor can also increase the dose to three CO-TRIMOXAZOLE 480 BIOTECH twice daily.

If you take more CO-TRIMOXAZOLE BIOTECH than you should

In the event of overdose diarrhoea, vomiting and nausea may occur. Consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

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Submitted: 22 August 2023**If you forget to take CO-TRIMOXAZOLE BIOTECH**

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. Do not take a double dose.

4. Possible side effects

CO-TRIMOXAZOLE BIOTECH can have side effects.

Not all side-effects reported for CO-TRIMOXAZOLE BIOTECH are included in this leaflet. Should your general health worsen while taking this medicine, please consult your healthcare provider for advice.

If any of the following happen, stop taking CO-TRIMOXAZOLE BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of mouth or tongue;
- Yellowing of the skin and eyes, also called jaundice;
- Skin rash or itching;
- Blistering or peeling of the skin;
- Unusual bleeding or bruising.

These are all very serious side effects. If you have them, you may have had a serious reaction to CO-TRIMOXAZOLE BIOTECH. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Greatly increased or decreased frequency of urination or amount of urine;
- Signs of frequent infections such as fever or sore throat.

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These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- A fungal infection called thrush which can affect your mouth or vagina
- High levels of potassium in your blood which can cause abnormal heart beats.
- Headache, dizziness, and fatigue
- Ringing or other noises in one or both ears
- Nausea, diarrhoea, vomiting, swollen and inflamed tongue, sore mouth
- Skin rash and itchy skin

Less frequent:

- inflammation (swelling, irritation) of the large intestine (symptoms include watery diarrhoea, stomach pain/cramps, fever, nausea)
- blood disorders that result in more frequent infections, unusual tiredness or weakness, easy or excessive bruising, bleeding from your gums or nose
- inflammation (swelling) of the pancreas (pancreatitis) characterized by abnormal pain that radiates to your back, fever, nausea and vomiting.
- thyroid gland grows larger. The thyroid gland is a small, butterfly-shaped gland located in the neck, below the Adam's apple.
- the thyroid gland doesn't create and release enough thyroid hormone into your bloodstream. The symptoms are fatigue, cold intolerance, weight gain, constipation and changes in voice.
- electrolyte imbalance, decreased appetite
- unstable moods, feeling depressed or seeing strange or unusual sights.
- inability to sleep, nightmares, sensation of moving or spinning, seizures

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- inflammation of the eye which causes pain and redness
 - coughing or a difficulty in breathing
 - abnormal liver function; yellowing of the skin, eyes
 - your skin gets irritated, might form a red, itchy patch or big fluid-filled blisters right in that same spot on your skin (fixed drug eruptions) every time there is exposure to the causative medicine
 - extreme sensitivity to sunlight
 - lower back pain, joint stiffness, muscle aches and pain
 - a serious syndrome due to a direct or indirect muscle injury (rhabdomyolysis). It results from the death of muscle fibers and release of their contents into the bloodstream. This can lead to serious complications such as kidney failure.
 - change in urinary frequency, pain or discomfort when urinating

Frequency unknown:

- skin condition marked by plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweet's syndrome)

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. 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 BIOTECH.

5. How to store CO-TRIMOXAZOLE BIOTECH

Store all medicines out of reach of children.

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Store in a dry place below 25° C and protect from light

Keep the medicine in the original container

Do not store the medicine in the bathroom

Do not use the tablets after the expiry date stated on the container, carton or 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 BIOTECH contains**

The active substances are trimethoprim and sulphamethoxazole

The other ingredients are maize starch, povidone K20, magnesium stearate.

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

CO-TRIMOXAZOLE 480 BIOTECH: White, round, flat, bevel-edged tablets, scored.

CO-TRIMOXAZOLE 960 BIOTECH: White, oblong tablets, scored.

CO-TRIMOXAZOLE 480 BIOTECH:

Amber glass bottles, sealed aluminum bags, securitainers or blister strips of 20, 40, 56 or 100 tablets.

Amber glass bottles, securitainers or blister strips of 500 tablets.

Blisters or amber plastic jars of 1 000 tablets.

LDPE Patient-ready-packs: 28 or 56 tablets.

CO-TRIMOXAZOLE 960 BIOTECH:

Amber glass bottles or securitainers of 10, 28, 30, 100, 250 or 500 tablets.

LDPE Patient-ready-packs: 28 or 56 tablets.

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Holder of Certificate of Registration

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