PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Co-Trimoxazole Pharma-Q Injection 5 ml solution for injection

Read all of this leaflet carefully before you are given Co-Trimoxazole Pharma-Q Injection 5 ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Co-Trimoxazole Pharma-Q Injection 5 ml** 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.

1. WHAT CO-TRIMOXAZOLE PHARMA-Q INJECTION 5 ml CONTAINS:

The active substances are trimethoprim and sulphamethoxazole

Each 5 ml contains: 80 mg trimethoprim and 400 mg sulphamethoxazole.

The other ingredients are benzyl alcohol, ethanol, propylene glycol, sodium hydroxide, sodium metabisulphite and water for injection.

2. WHAT CO-TRIMOXAZOLE PHARMA-Q INJECTION 5 ml IS USED FOR:

Co-Trimoxazole Pharma-Q Injection 5 ml is a sulphonamide antibiotic combination of trimethoprim and sulphamethoxazole and it is used to treat a variety of bacterial infections. Trimethoprim and sulphamethoxazole used in combination because they have a greater effect when they are used together than when each is given separately. They cause a blockade of two consecutive steps in the production of folic acid, which is an important chemical for the synthesis of bacteria. Hence bacteria can no longer multiply.

Your doctor has prescribed **Co-Trimoxazole Pharma-Q Injection 5 ml** for you because you may be suffering from one of the following infections:

- Infections involving both the genital and urinary tract
- Infections of the respiratory system; including pneumonia (inflammation of the lungs) and pneumocystis carinii pneumonitis (pneumonia in infants and weakened patients such as those with AIDS)
- Infections which involve the digestive tract; i.e. anywhere from the mouth to the anus; including shigellosis (caused by bacteria called *Shigella* and results in diarrhoea, fever and stomach cramps) and typhoid fever (transmitted by eating food or water contaminated with faeces of an infected person and contain the bacterium called *Salmonella*)
- Other bacterial infections caused by sensitive organisms: Brucellosis (caused by ingestion of unsterilized milk or meat from infected animals) and septicaemia (blood poisoning).

3. BEFORE YOU ARE ADMINISTERED CO-TRIMOXAZOLE PHARMA-Q INJECTION 5 ml:

You should NOT be administered Co-Trimoxazole Pharma-Q Injection 5 ml:

- If you have a history of allergic reactions to co-trimoxazole, the sulphonamides, sulpha medicines or trimethoprim
- If you suffer from severe kidney or liver failure; unless your doctor monitors your blood concentrations of these medicines
- If you suffer from blood disorders or impairments; unless your doctor monitors your blood concentrations of these medicines
- If you suffer from jaundice (too much bile in your blood causing a yellow colour to the skin, gums, eyes, etc.)

- If you suffer from megaloblastic anaemia (blood disorder in which there is a reduction in healthy red blood cells which provide oxygen to body tissues, because your body does not absorb enough vitamin B_{12} from the digestive tract)
- If you suffer from acute porphyria (disturbance of metabolism which cause disorders of the skin or other organs) as the sulphamethoxazole component may cause exacerbations of the disease
- If the patient is an infant. It will not be given to infants within 1 to 2 months of birth because of the risk of producing kernicterus (brain damage caused by excessive jaundice)
- If you are pregnant or breastfeeding (see **Pregnancy and Breastfeeding**).

Tell your doctor or healthcare professional before being given Co-Trimoxazole Pharma-Q Injection 5 ml:

Special care should be taken with Co-Trimoxazole Pharma-Q Injection 5 ml:

Co-Trimoxazole Pharma-Q Injection 5 ml:

- Will be avoided if you suffer from a deficiency of the enzyme called glucose 6 phosphate dehydrogenase (this deficiency causes blood disorders such as haemolytic anaemia, a condition in which red blood cells are prematurely destroyed-see **POSSIBLE SIDE-EFFECTS**)
- Will be used with caution if you suffer from impaired kidney function and your dosage may need to be adjusted
- Your fluid intake will be maintained to reduce your risk of crystalluria (crystals in the urine)
- Your doctor will carry out regular blood counts, kidney function tests and analysis of your urine, if you are receiving prolonged treatment with this injection
- If you are old, you may be more susceptible to the occurrence of adverse effects

- You may be given folate supplementation (folates essential for numerous body functions) if you are predisposed to folate deficiency. This occurs more often if you are old, or if you are on high doses of therapy over prolonged periods of time.

Also take special care:

Co-Trimoxazole Pharma-Q Injection 5 ml:

The sulphamethoxazole component:

- Your treatment will be immediately discontinued if a rash appears. This is because of the danger of severe allergic reactions such as the Stevens-Johnson syndrome (extremely serious allergic reaction)
- Your risk of crystalluria will be reduced by the administration of adequate fluids to maintain a high urine output. If necessary, you may be given sodium bicarbonate to increase the solubility and help with the elimination of this medicine
- It will be administered with care if you have a history of allergy or asthma (narrowing of the airways)
- It will also be administered with care if you are old.

The trimethoprim component:

- You will not be given this medicine if you have a history of allergic reactions to this medicine
- It will be discontinued if a skin rash appears
- It will be administered with care if you suffer from impaired kidney function, in order to avoid accumulation in the body and toxicity
- It will not be given to you if you suffer from severe kidney impairment unless your blood concentrations are regularly monitored by your doctor
- It will be used with caution if you suffer from severe liver damage
- You will undergo regular blood examinations if you are on prolonged courses of this treatment

- It will not usually be given to you if you suffer from serious blood disorders and particularly not if you suffer from megaloblastic anaemia (anaemia due to decreased vitamin B_{12} absorption) secondary to folate depletion (folates essential for body functions).

Co-trimoxazole:

If you suffer from AIDS (Acquired Immune Deficiency Syndrome), you may be at a higher risk of experiencing adverse reactions to Co-trimoxazole.

Pregnancy and Breastfeeding:

Co-Trimoxazole Pharma-Q Injection 5 ml:

You will not be given Pharma-Q Co-Trimoxazole Injection if you are pregnant or breast-feeding (see **You should NOT be given Co-Trimoxazole Pharma-Q Injection 5 ml**).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before you receive **Co-Trimoxazole Pharma-Q Injection 5 ml.**

Driving and using machinery:

Co-Trimoxazole Pharma-Q Injection 5 ml may cause dizziness, drowsiness and fatigue. You should not drive or use machinery if you are affected by the adverse effects of **Co-Trimoxazole Pharma-Q Injection 5 ml.**

Using other medicines with Co-Trimoxazole Pharma-Q Injection 5 ml:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Co-Trimoxazole Pharma-Q Injection 5 ml may interact with other medicines:

The sulphamethoxazole component:

- Sulphonamides may increase the effects of some agents, such as oral anticoagulants (medicines used to prevent blood clots), methotrexate (medicines used in cancer and certain skin conditions) and phenytoin (medicines used to treat fits)
- High doses of sulphonamides may decrease blood sugar levels; the antidiabetic effect of the sulphonylurea compounds (medicines used to lower blood sugar levels) may be enhanced by the concomitant administration of sulphonamides
- The action of sulphonamides may be antagonised by para-aminobenzoic acid (nutrient in our body) and compounds derived from it, particularly the procaine group of local anaesthetics
- Sulphonamides may interfere with some diagnostic tests e.g. kidney functioning tests.

The trimethoprim component:

- In elderly patients, trimethoprim may increase blood concentrations and increase the effect of a number of medicines, including phenytoin (medicine used to treat fits, digoxin (medicine used for the heart) and procainamide (medicine used for abnormal rhythms of the heart)
- Trimethoprim and dapsone (antibiotic) increase each other's blood concentrations when given concomitantly, whereas rifampicin (antibiotic) may decrease trimethoprim concentrations
- The use of trimethoprim concomitantly with diuretics (medicines which increase urine output) may cause hyponatraemia (decreased sodium levels in blood)
- Administration of trimethoprim with other medicines which depress bone marrow function, may increase the likelihood of myelosuppression (decreased production of blood cells by the bone marrow) and there may be a particular risk of megaloblastic

anaemia if it is given with other folate inhibitors such as pyrimethamine (medicines used for malaria) or methotrexate (medicines used for cancer)

- Trimethoprim may also interfere with some diagnostic tests.

Co-trimoxazole (both components together):

- An increased risk of toxicity to the kidney may occur with the administration of trimethoprim or co-trimoxazole concomitantly with ciclosporin (medicine used to reduce the activity of the immune system)
- Administration of trimethoprim and sulphonamides directly into the vein may reduce ciclosporin concentrations in blood
- An increased risk of too few blood platelets may occur in elderly patients when Co-trimoxazole is given concomitantly with diuretics (medicines used to increase urine output).

4. HOW TO RECEIVE CO-TRIMOXAZOLE PHARMA-Q INJECTION 5 ml:

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

Always receive **Co-Trimoxazole Pharma-Q Injection 5 ml** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

Co-Trimoxazole Pharma-Q Injection 5 ml will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you or your child.

Co-Trimoxazole Pharma-Q Injection 5 ml:

- Will be given by intravenous infusion only (directly into the vein)
- It will not be injected into the muscle or under the skin
- It will be diluted immediately before use
- It will be infused (given by drip) over 60 to 90 minutes
- Your dosage will be calculated by your doctor

- Dosages will be reduced for children under 12 years of age
- It will be administered twice daily
- As soon as oral treatment becomes possible, the intravenous administration will be discontinued.

If you have the impression that the effect of **Co-Trimoxazole Pharma-Q Injection 5 ml** is too strong or too weak, talk to your doctor or pharmacist.

If you receive more Co-Trimoxazole Pharma-Q Injection 5 ml than you should:

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection.

For symptoms of overdosage see **POSSIBLE SIDE EFFECTS**.

Co-Trimoxazole Pharma-Q Injection 5 ml overdosage:

- You may suffer from diarrhoea, nausea, vomiting, skin rashes and other allergic reactions with high doses
- You may suffer from decrease in blood production
- You may be given injections of calcium folinate to counteract this effect
- You will undergo frequent blood counts, particularly if you are on prolonged therapy
- If severe, life-threatening allergic reactions occur, you will be given supportive measures i.e. cortisone, intravenous infusion, adrenaline etc.
- Your treatment will be aimed at treating your symptoms as well as giving you medical support.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of Co-Trimoxazole Pharma-Q Injection 5 ml:

If you think that you did not receive a dose of **Co-Trimoxazole Pharma-Q Injection 5 ml**, contact your doctor.

If you have any further questions on the use of **Co-Trimoxazole Pharma-Q Injection 5 ml**, ask your doctor, nurse, or pharmacist.

5. POSSIBLE SIDE EFFECTS:

Co-Trimoxazole Pharma-Q Injection 5 ml can have side effects.

Not all side effects reported for **Co-Trimoxazole Pharma-Q Injection 5 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **Co-Trimoxazole Pharma-Q Injection 5 ml**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following serious side effects occur, stop receiving Co-Trimoxazole Pharma-Q Injection 5 ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **Co-Trimoxazole Pharma-Q Injection 5 ml.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- yellowing of the skin and eyes, also called jaundice.

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

Tell your doctor as soon as possible if you notice any of the following:

Sulphamethoxazole:

The sulphamethoxazole component may cause side effects but the frequencies are unknown:

Blood and the lymphatic system disorders:

Frequency unknown: Severe decrease in a particular type of white blood cell, aplastic anaemia (bone marrow does not produce enough new cells to replenish blood cells), too few blood platelets, too few white blood cells, blood disorder which results in impaired blood clotting and increased number of white blood cells called eosinophils. Acute haemolytic anaemia (a condition in which red blood cells are prematurely destroyed- (see **Special care should be taken with Co-Trimoxazole Pharma-Q Injection 5 ml**) is a complication which may be associated with glucose-6-phosphate dehydrogenase deficiency.

Endocrine disorders:

Frequency unknown: Decreased blood sugar levels and decreased thyroid function.

Nervous system disorders:

Frequency unknown: Aseptic meningitis (inflammation of the meninges of the brain which is not caused by a bacterial infection), uncontrolled muscle movement, increased pressure inside the skull which is benign, fits, dizziness, drowsiness, fatigue, headache, inability to sleep, mental depression, damage to nerves in the eyes or peripheral nerve damage, mental disorders and vertigo.

Gastro-intestinal disorders:

Frequency unknown: Nausea, vomiting, loss of appetite and diarrhoea.

Hepato-biliary disorders:

Frequency unknown: Sulphonamides may displace serum bound bilirubin, resulting in jaundice and kernicterus (form of brain damage caused by excessive jaundice) in premature neonates.

Skin and subcutaneous disorders:

Frequency unknown: Rashes, increased sensitivity to sunlight, excessive peeling of the skin, detachment of the outermost layer of skin from the underlying layers (Lyell's syndrome) and erythema nodosum (red inflamed nodules in the fatty layer of the skin).

A severe, potentially fatal, form of erythema multiform, associated with widespread lesions of the skin and mucous membranes, termed the Stevens-Johnson syndrome may occur.

Systemic lupus erythematosus (chronic disorder of connective tissue in which there can be skin rash, arthritis, etc.), particularly exacerbations of pre-existing disease, may also occur, as well as severe life-threatening allergic reactions.

Renal and urinary disorders:

Frequency unknown: Toxicity of the kidney due to chemicals, including interstitial nephritis (inflammation of the kidney) and tubular necrosis (death of cells which make up the tubes that carry urine), which may result in kidney failure. Lower back pain, blood in the urine, decreased amount of urine and no urine being made, may also occur due to the formation of crystals of sulphamethoxazole or its less soluble metabolite in the urine.

General disorders and administrative site conditions:

Frequency unknown: Fever and a syndrome resembling serum sickness (allergic reaction), death of liver tissue, enlarged liver, yellow pigmentation of skin and eyes, inflammation of the heart muscle, inflammation of the pancreas, inflammation of the lungs due to an increase in a type of white blood cell called eosinophils, fibrosing alveolitis (lung disease) and vasculitis (inflammatory destruction of blood vessels) including polyarteritis nodosa (destruction of medium and small arteries). Sulphonamides may also cause blue colour to skin and gums

due to methaemoglobinaemia (increased levels of methemoglobin in the blood which has a higher affinity for oxygen and thus releases less oxygen to tissues).

Trimethoprim:

The trimethoprim component may cause side effects but the frequencies are unknown:

Blood and the lymphatic system disorders:

Frequency unknown: Decreased production of blood cells. This may manifest as megaloblastic anaemia (blood disorder in which there is a reduction in healthy red blood cells which provide oxygen to body tissues, because your body does not absorb enough vitamin B_{12} from the digestive tract) or as too few blood platelets and too few white blood cells. Increased levels of methemoglobin (has a higher affinity for oxygen and thus releases less oxygen to tissues) may also occur.

Nervous system disorders:

Frequency unknown: Aseptic meningitis (inflammation of the meninges of the brain which is not bacterial in nature).

Gastro-intestinal disorders:

Frequency unknown: Mild gastro-intestinal disturbances including nausea, vomiting and sore mouth.

Skin and subcutaneous disorders:

Frequency unknown: Itching, skin rash, excessive peeling of the skin, red inflamed nodules in the fatty layer of the skin and detachment of the top layer of skin from the underlying layers. Occasionally, allergic reactions may be severe and manifest as severe life-threatening allergic reactions.

Hepato-biliary disorders:

Frequency unknown: Disturbances of liver enzyme values and cholestatic jaundice (obstruction in the flow of bile from the liver to the intestine)

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

6. STORING AND DISPOSING OF CO-TRIMOXAZOLE PHARMA-Q INJECTION 5 ml:

Store at or below 25 °C.

Protect from light.

Keep all medicine out of reach of children.

7. PRESENTATION OF CO-TRIMOXAZOLE PHARMA-Q INJECTION 5 ml:

5 ml ampoules in boxes of 10's

8. IDENTIFICATION OF CO-TRIMOXAZOLE PHARMA-Q INJECTION 5 ml:

A clear colourless, to slightly yellow solution, filled in 5 ml clear colourless ampoules.

9. REGISTRATION NUMBER:

29/20.2/0665

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

South Africa

Pharma-Q Holdings (Pty) Ltd	Co-Trimoxazole Pharma-Q Injection 5 ml	Solution for injection
		80 mg trimethoprim and 400 mg sulphamethoxazole/5 ml

11. DATE OF PUBLICATION:

26 June 2024