

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Co-trimoxazole 960 mg tablets

(Sulfamethoxazole and Trimethoprim)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

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

### 1. What Co-trimoxazole tablet is and what it is used for

Co-trimoxazole tablets are made up of two different medicines called sulfamethoxazole & trimethoprim. These medicines are sometimes given the combined name Co-trimoxazole. Both belong to the group of medicine called antibiotics. They are used to treat infections caused by Specific bacteria. This means that it is only suitable for treating some type of infections.

### Co-trimoxazole tablets are used to treat or prevent:

- Lung infections (Pneumonia or Pneumocystis pneumonia) caused by a bacteria called *Pneumocystis jiroveci* (previously known as *Pneumocystis carinii*)
- Infection caused by a bacterium called Toxoplasma (toxoplasmosis)

### Co-trimoxazole tablets are used to treat:

- Bladder or urinary tract infections (water infection)
- Acute worsening of chronic bronchitis due to bacterial infection.
- Ear infections such as otitis media
- An infection called nocardiosis, which can affect the lungs, skin and brain.

### 2. What you need to know before you take Co-trimoxazole tablets

#### Do not take Co-trimoxazole tablets:

- You are allergic to sulfamethoxazole, trimethoprim or any of the other ingredient of Co-trimoxazole tablets (listed in section 6).
- You are allergic to other sulphonamide medicines. These include sulphonylurea (such as gliclazide and glibenclamide used to treat diabetes) or thiazide diuretics (such as bendroflumethiazide – a water tablet)
- You have liver problems like marked liver damage.
- You have severe renal insufficiency.
- You suffer from porphyria, a genetic disease which can affect your skin or nervous system.
- Co-trimoxazole 160 mg/800 mg tablets are not suitable for children under 12 years old.

### Warnings and precautions

Before you take Co-trimoxazole tablets, tell your doctor or pharmacist if:

- You have severe allergies or asthma.
- You have ever had an allergic skin reaction such as Stevens – Johnson syndrome, toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS).
- If you have previously developed Stevens-Johnson syndrome or toxic epidermal necrolysis and DRESS with the use of Co-trimoxazole tablets you must not be re-started on Co-trimoxazole tablets at any time.
- If you develop a rash or these skin symptoms, stop taking Co-trimoxazole tablets, seek urgent advice from a doctor and tell him that you are taking this medicine.
- You have a rare disease called porphyria, you should not take Co-trimoxazole tablets as it can lead to acute worsening of your condition.
- If you have a serious disease affecting your blood. Co-trimoxazole tablets can affect the bone marrow and stop it from producing red or white blood cells.
- If you suffer from an abnormality called 6 GDP deficiency- taking Co-trimoxazole tablets may lead to destruction of red blood cells.
- If you are dehydrated, as the risk of kidney damage or kidney stones while taking Co-trimoxazole tablets is increased. You should take plenty of fluids while taking Co-trimoxazole tablets unless otherwise advised by your doctor.
- 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 and cause a particular type of anaemia. You may have to take folic acid supplements, particularly if you are elderly.

- You have problem with metabolism called phenylketonuria and are not on special diet to help your condition.
  - You are elderly.
  - You are underweight or malnourished.
  - You have high levels of potassium in your blood.
  - You have had severe diarrhoea whilst taking antibiotics in the past
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-trimoxazole tablets.

### Other medicines and Co-trimoxazole tablets

Tell your doctor if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Co-trimoxazole tablets can affect the way some medicine work. Also some medicine can affect the way Co-trimoxazole tablets works:

In particular, tell your doctor or pharmacist if you are taking any of following medicines

- Diuretics (water tablets), which help increase the amount of urine you produce.
- Pyrimethamine, used to treat and prevent malaria, and to treat toxoplasmosis.
- Ciclosporin, used after kidney transplants
- Warfarin used to the thin blood.
- Phenytoin used to treat epilepsy (fits)
- Medicine for diabetes, such as glibenclamide, glipizide or tolbutamide (Sulphonylureas)
- Medicine to treat problems with the way your heart beats such as digoxin or procainamide.
- Amantadine, used to treat Parkinson's disease, multiple sclerosis, flu or shingles.
- Medicine to treat HIV (Human Immunodeficiency Virus) such as zidovudine or lamivudine.
- Medicine that can increase amount of potassium in your blood, such as potassium sparing diuretics (water tablets)
- Methotrexate, a medicine used to treat cancer for or diseases involving your immune system.
- Spironolactone, a medicine used to treat fluid retention and hypokalaemia.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-trimoxazole tablets.

### Use in children

Co-trimoxazole tablets are not suitable for children aged 12 or under.

### Co-trimoxazole tablets with food and drink

You should take Co-trimoxazole tablets with some food or drink. This will stop you feeling sick (nausea) or having diarrhea. Although it is better to take it with food, you can still take it on an empty stomach.

Drink plenty of fluid such as water while you are taking Co-trimoxazole tablets.

### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

### Driving and using machines

While taking Co-trimoxazole tablets you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) and vertigo. If this happens, do not drive or use any machinery.

### 3. How to take Co-trimoxazole tablets

Always take Co-trimoxazole tablets exactly as your doctor has told you. The label on your pack will tell you how much to take and how often to take it. Check with your doctor or pharmacist if you are not sure.

### Usual Dose:

Adults and adolescents above the age of 12 years

- The usual dose is one tablet in morning and one tablet in an evening.
- Co-trimoxazole tablets should be taken for at least 5 days.
- Make sure that you finish the course of Co-trimoxazole tablets which your doctor has prescribed.

### Special Dose

The dose of Co-trimoxazole tablets how long you need to take it depends on the infection you have and how bad it is. Your doctor may prescribe you a different dose or length of course of Co-trimoxazole tablets to

- Treat urinary tract (water) infections
- Treat and prevent lung infection caused by bacteria *Pneumocystis jiroveci*
- Treat infection caused by bacteria toxoplasma (Toxoplasmosis) or Nocardia (nocardiosis).

### If you have kidney problem your doctor may

- Prescribe lower dose of Co-trimoxazole tablets.
- Take blood test whether medicine is working properly.

**If you take Co-trimoxazole tablets for long time your doctor may**

Take blood test whether medicine is working properly.

Prescribe folic acid (a vitamin) for you to take at the same time as Co-trimoxazole tablets.

**If you take more Co-trimoxazole tablets than you should**

If you take more Co-trimoxazole tablets than you should, talk to your doctor or go to hospital straight away. Take the medicine pack with you.

**If you have taken too much Co-trimoxazole tablets**, you may feel or be sick and feel dizzy or confused.

**If you forget to take Co-trimoxazole tablets**

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 a forgotten dose.

**4. Possible side effects**

Like all medicines, Co-trimoxazole tablets can cause side effects, although not everybody gets them.

You may experience the following side effects with this medicine.

Stop taking Co-trimoxazole tablets and tell your doctor immediately if you have allergic reaction. Chance of an allergic reaction is very rare (fewer than 1 in 10,000 people are affected), signs of allergic reaction include.

**Allergic reactions**

- Difficulty in breathing
- Fainting
- Swelling of face
- Swelling of mouth, tongue or throat which may be red and painful and/or cause difficulty in swallowing
- Chest pain
- Red patches on skin

Life-threatening cutaneous reactions (Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)) have been reported with the use of Co-trimoxazole tablets. There appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. If you develop a rash or these skin symptoms, stop taking Co-trimoxazole tablets, seek urgent advice from a doctor and tell him that you are taking this medicine.

If you develop watery and severe diarrhoea, which may also be bloody, stop taking Co-trimoxazole tablets and speak to your doctor straight away.

**Very Common (more than 1 in 10 people)**

- High level of potassium in your blood, which can cause abnormal heart beats (palpitations).

**Common (less than 1 in 10 people)**

- An infection caused by candida called thrush or candidiasis which can affect your mouth or vagina.
- Headache
- Feeling sick (nausea)
- Diarrhoea
- Skin rashes.

**Uncommon (less than 1 in 100 people)**

- Being sick (vomiting)

**Very rare (less than 1 in 10,000 people)**

- Abnormalities affecting the blood such as Reduced formation of red and white blood cells or destruction of red blood cells (haemolytic anaemia)
- A decrease in the number of white cells in your blood (leucopenia, neutropenia), which increases your risk of infection. The signs may include high temperature (fever), shivering and a sore throat.
- Feeling weak, short of breath, tired or listless, pale skin (anaemia)
- Bleeding or bruising more than usual. This may be because the level of platelets in your blood has dropped (thrombocytopenia).
- Fever (high temperature)
- Sudden wheeziness or difficulty breathing
- Mouth ulcers, cold sores and ulcers or soreness of your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on your skin or inside your mouth, nose, vagina or bottom
- Inflammation of eye which causes pain and redness.
- The appearance of a rash or sunburn when you have been outside (even on cloudy day)
- Low levels of sodium in your blood
- Heart problems (inflammation of the heart muscle).
- Narrowing or blockage of blood vessels (vasculitis), unusual bleeding or bruising under the skin.
- Abnormal liver function tests, liver damage

- Jaundice (the skin and whites of your eyes turn yellow). This can occur at same time as unexpected bleeding or bruising
- Pains in your stomach, which can be caused by an inflammation of the pancreas.
- Inflammation of the large bowel which can cause stomach pains & fever with diarrhoea, usually with blood & mucus
- Pains in your chest, muscles or joints and muscle weakness, arthritis
- Abnormal kidney function, inflammation of the kidney
- Sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- Problems controlling your movement.
- Fits (convulsion or seizures)
- Feeling unsteady or giddy.
- Ringing or other unusual sounds in your ears
- Tingling or numbness in your hands and feet
- Seeing strange or unusual sights (hallucinations)
- Depression
- Muscle pain and/or muscle weakness in HIV patients.

**Not known**

- Drug reaction with eosinophilia and systemic symptoms (DRESS)

If you get any side effects or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Co-trimoxazole tablets**

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use Co-trimoxazole tablets after the expiry date stated on the label and carton. The expiry date refers to the last day of that month.

Store in the original package with this leaflet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Co-trimoxazole tablets contains**

Co-trimoxazole tablets are made up of two different medicines called Sulfamethoxazole & Trimethoprim. These medicines are sometimes given the combined name Co-trimoxazole.

- The active substances are Sulfamethoxazole 800 mg and Trimethoprim 160 mg.
- The other ingredients are docusate sodium, magnesium stearate, sodium starch glycolate (type A), and povidone (PVP K 30).

**What Co-trimoxazole tablets looks like and contents of the pack**

Co-trimoxazole tablets are white, uncoated, standard curvature with one side breakline, capsule shaped tablets.

Co-trimoxazole tablets are supplied to you in:

Blister pack: PVC and Aluminum foil

Pack sizes are 10, 14 (with and without calendar pack), 28 (with and without calendar pack), 30, 50 and 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

DAWA Limited, 5 Sandridge close, Harrow, Middlesex HA1 1XD, UK

**Manufacturer**

Drugsrus Limited, 5 Sandridge close, Harrow Middlesex, HA1 1XD, UK

**This leaflet was last revised in 12/2016**