

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

EMBRACOTRIM 960

[Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg]

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 health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet.

What is in this leaflet:

1. What Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg is and what it is used for
2. What you need to know before you take Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg
3. How to take Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg
4. Possible side effects
5. How to store Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg
6. Contents of the pack and other information

1. WHAT TRIMETHOPRIM AND SULFAMETHOXAZOLE TABLETS BP 160 MG/800 MG IS AND WHAT IT IS USED FOR

Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg is a combination of two antibiotics: sulfamethoxazole and trimethoprim. Antibiotics stop the growth of bacteria (bugs) which cause infections.

In patients with human immunodeficiency virus (HIV)/AIDS, Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg can be used to treat or stop you from getting:

- lung infections (pneumonia or PJP) caused by an organism called *Pneumocystis jiroveci*
- middle ear infection
- brain infection caused by a parasite called *Toxoplasma* (toxoplasmosis encephalitis)
- urinary bladder or urinary tract infections
- chest infections in patients with chronic bronchitis
- infection caused by bacteria called *Nocardia* that can affect the lungs, skin/brain (nocardiosis)
- infection caused by bacteria called *Brucella* (brucellosis) together with another antibiotic

In patients with HIV/AIDS, Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg may be given to stop you from getting malaria. Malaria is spread by the bite of an infected mosquito, which passes the malaria parasite (*Plasmodium falciparum*) into the bloodstream.

Sulfamethoxazole/trimethoprim prevents malaria by killing this parasite.

Mechanism of action: Sulfamethoxazole/trimethoprim interferes with the bacterial synthesis of tetrahydrofolic acid, an essential stage in the production of thymidine, purines and subsequently nucleic acids. Sulfamethoxazole inhibits the formation of dihydrofolic acid from p-aminobenzoic acid; trimethoprim inhibits the action of the enzyme dihydrofolate reductase, thus preventing the synthesis of tetrahydrofolic acid from dihydrofolic acid. Thus the combination of trimethoprim and sulfamethoxazole blocks two consecutive steps within the bacterial metabolic pathway of the biosynthesis of nucleic acids and proteins.

Sulfamethoxazole/trimethoprim usually shows in vitro activity against the following gram-negative and gram-positive organisms, e.g. *E. coli*, *Neisseria*, *Salmonella*, *Klebsiella*, *Enterobacter*, *Shigella*, *Vibrio*

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cholerae, Bordetella pertussis, Streptococcus, Staphylococcus, Pneumococcus, Haemophilus influenzae and Proteus.

Sulfamethoxazole/trimethoprim is also active against the protozoan Pneumocystis jirovecii. However, Mycobacterium tuberculosis, Treponema pallidum, Mycoplasma and Pseudomonas aeruginosa are frequently resistant to sulfamethoxazole/trimethoprim

Pharmacotherapeutic group: ANTIBACTERIALS FOR SYSTEMIC USE – SULFONAMIDES AND TRIMETHOPRIM Combinations of sulphonamides and trimethoprim, incl. derivatives,

ATC code: J01EE01.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRIMETHOPRIM AND SULFAMETHOXAZOLE TABLETS BP 160 MG/800 MG

Do not take Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg if you:

- are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or the combination of these (sometimes also called co-trimoxazole), or any of the other ingredients of Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg (see section 6: Contents of the pack and other information).
- are allergic to sulphonamide medicines, for example sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – which increases the amount of urine you pass)
- have developed Stevens-Johnson syndrome or toxic epidermal necrolysis (severe skin reactions involving itching, reddening and blistering of the skin) with the use of sulfamethoxazole/trimethoprim
- have severe liver or kidney problems
- have ever had a problem with your blood, such as a low number of red blood cells which may make your skin pale yellow and cause weakness or breathlessness (megaloblastic anaemia), or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia)
- have been told that you have or are at risk of getting a rare blood problem called porphyria, which can affect your skin or nervous system

Sulfamethoxazole/trimethoprim should not be taken together with:

- clozapine (used to treat schizophrenia, a mental illness)
- sulfadoxine, pyrimethamine or amodiaquine (used to treat or stop you from getting malaria)

Combining any of these drugs with Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg can cause serious side effects. Consult your health care provider for advice on alternative medicines.

This medicine should not be given to a child who is less than 6 weeks old.

If you are not sure if any of the above apply to you, talk to your health care provider before taking sulfamethoxazole/trimethoprim.

Warnings and precautions

If you develop a severe hypersensitivity reaction, stop taking this medicine and seek urgent advice from a health care provider and say that you are taking this medicine. Signs may include sudden swelling of the throat or face which might make it difficult to breath or swallow, sudden swelling of the hands, feet and ankles or severe rash. Rash may appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for are 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.

Talk to your health care provider before taking Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg if you:

- have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause break-down of red blood cells and jaundice.
- have a problem with your metabolism called phenylketonuria
- have a severe blood disorder, such as a low number of white blood cells (leucopenia)
- are underweight or malnourished
- have been told by your health care provider that the potassium level in your blood is too high
- your kidneys or liver are not working well
- don't have enough folic acid (a vitamin) in your body - which can make you look pale and make you feel tired, weak and breathless (anaemia)
- have recently had diarrhoea after having an antibiotic medicine or have ever had problems with your gut, in particular colitis (inflammation of the bowel)

If you are given Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg for a long time, you may need to have regular urine and blood tests and you may be given folic acid. You may have urine and blood tests if your kidneys are not working well.

Taking other medicines

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg can affect the way some medicines work. Also some other medicines can affect the way Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg works.

In particular tell your health care provider if you are taking any of the following medicines:

- thiazides which are medicines that increase the amount of urine you produce
- dapson, used to treat certain infections
- ciclosporin, used after organ transplantation
- coumarins, which are medicines used for preventing blood clots, such as warfarin.
- phenytoin, used to treat epilepsy (fits)
- medicines used to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulfonylureas), repaglinide, pioglitazone or metformin
- digoxin or procainamide which are medicines to treat heart conditions
- amantadine, used to treat Parkinson's disease
- medicines that can increase the amount of potassium in your blood, such as certain diuretics (which help increase the amount of urine you produce) and some blood pressure and heart medicines
- lamivudine, a medicine used to treat HIV (human immunodeficiency virus) infection
- folic acid
- medicines that stop the bone marrow from working properly and/or decrease the number of blood cells in the body. Examples are:
 - methotrexate, a medicine used to treat certain cancers or certain diseases affecting your immune system such as rheumatoid arthritis and psoriasis
 - zidovudine, a medicine used to treat HIV (human immunodeficiency virus) infection
 - ganciclovir, which is used for treating CM (cytomegalovirus) infection
 - pyrimethamine, used to treat an infection called toxoplasmosis

Taking Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg with food and drink

You can take your medicine with food or between meals.

Pregnancy and breast-feeding

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

Driving and using machines

Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg may cause dizziness. If you feel dizzy while taking Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg, do not drive and do not use hazardous tools or machines.

3. HOW TO TAKE TRIMETHOPRIM AND SULFAMETHOXAZOLE TABLETS BP 160 MG/800 MG

Always take your medicine exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

These tablets are not suitable for patients who cannot swallow tablets. You may break the tablet in half if necessary but you (or your child) must not crush or chew the tablets.

Taking it with food may help to stop you feeling sick (nausea). Drink plenty of fluid such as water while you are taking this medicine.

Usual dose

Adults and adolescents over 12 years and weighing more than 40 kg:

1 tablet in the morning and 1 tablet in the evening

Children younger than 12 years and weighing up to 40 kg:
In children the dose is calculated based on body weight.

Body weight	20 to 40 kg
Dose	½ tablet twice daily

Special dose for specific situations

In certain circumstances your health care provider may prescribe a different dose or treatment duration. The dose of Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg and how long you need to take it depends on the infection you have and how bad it is:

- To treat a lung infection caused by *Pneumocystis jiroveci*, the dose is calculated based on body weight: 25 mg/kg sulfamethoxazole and 5 mg/kg trimethoprim, 3 to 4 times daily for 14 to 21 days.
- To treat a brain infection caused by *Toxoplasma* (toxoplasmosis encephalitis), the dose is calculated based on body weight: 25 mg/kg sulfamethoxazole and 5 mg/kg trimethoprim, 2 times daily.
- To treat infections caused by *Nocardia* (nocardiosis), your health care provider will decide the right dose for you. A dose of 50 mg/kg sulfamethoxazole and 10 mg/kg trimethoprim per day has been prescribed to adults.
- Treat infections caused by *Brucella* (brucellosis):

Adults and children over 12 years and weighing over 32 kg:

1 tablets in the morning and 1 tablet in the evening for 6 weeks. If you have severe infection, your health care provider may decide to treat you for more than 6 weeks.

Children younger than 12 years and weighing up to 32 kg:

The dose is calculated based on body weight: 25 mg/kg sulfamethoxazole and 5 mg/kg trimethoprim, two times daily, for 6 weeks. If your child has severe infection, your health care provider may decide to treat your child for more than 6 weeks.

- To prevent the infections listed above and malaria
Adults and adolescents (10 years and older and weighing more than 25 kg):
1 tablet per day.

Children:

In children the dose is calculated based on body weight.

Body weight	14.0 to 24.9 kg
Dose	½ tablet once daily

If you have kidney problems your health care provider may prescribe a lower dose of Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg.

If you take more Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg than you should

If you accidentally take too many tablets, immediately contact your health care provider or nearest emergency department. Take the tablet container with you so that you can easily describe what you have taken. If you have taken too much sulfomethoxazole/trimethoprim, you may feel or be sick, feel dizzy or confused.

If you forget to take Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg

It is important not to miss a dose. If you miss a dose of this medicine, contact your health care provider for advice. Do not take a double dose to make up for a forgotten tablet.

If you vomit less than 1 hour after taking this medicine, take another dose. You do not need to take another dose if you were sick more than 1 hour after taking Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg

If you stop taking Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg

Don't stop taking this medicine without checking with your health care provider. Stopping your tablets too early may no longer protect you from the infection or cause it to come back.

If you have any further questions on the use of this medicine, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg can cause side effects, although not everybody gets them.

You may develop an allergic reaction to this medicine. Chances of an allergic reaction are very rare (fewer than 1 in 10,000 people are affected).

Tell your health care provider immediately if you have an allergic reaction and do not take any more Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg.

In addition, if any of the following side effects gets serious, or if you notice any other unexpected or unusual symptoms not listed in this leaflet, please tell your health care provider.

Very common side effects

(may affect more than 1 in 10 people):

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

Common side effects

(may affect up to 1 in 10 people):

- a fungal infection called thrush or candidiasis which can affect for example your mouth or vagina.
- headache
- feeling sick (nausea)
- diarrhoea
- skin rashes

Uncommon side effects

(may affect up to 1 in 100 people)

- being sick (vomiting)

Very Rare side effects

(may affect up to 1 in 10 000 people)

- sudden wheeziness or difficulty breathing
- extreme tiredness, abnormal bruising or bleeding or signs of infection, such as sore throat and high temperature. These may be signs of reduced:
 - red blood cells, which can make the skin pale and cause weakness or breathlessness (anaemia),
 - blood platelets (that help to stop bleeding) and
 - white blood cells (that help defend against infections)
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Henoch-Schonlein purpura (a rash which appears as purple spots on the skin)
- mouth ulcers, cold sores and ulcers or soreness of your tongue
- blisters on your skin or inside your mouth, nose, vagina or bottom
- inflammation of your eye which causes pain and redness
- rash or sunburn when you have been outside (even on a cloudy day)
- abnormal blood tests, including low levels of sodium in your blood
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. This can occur at the same time as unexpected bleeding or bruising.

- severe diarrhoea containing blood or mucus (antibiotic associated colitis including pseudomembranous colitis), which in rare circumstances may develop into complications that are life-threatening.
- muscle or joint pain and muscle weakness
- excessive breakdown of muscle tissue which can result in muscle pain, dark urine and kidney problems with your urine. Difficulty passing urine. Passing more or less urine than usual.
- kidney problems (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)
- sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- problems controlling your movement
- fits (convulsions 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
- loss of appetite
- inflammation of the pancreas (symptoms may include severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting)

Side effects of which it is not known how often they may occur

- abnormal heart rhythm (torsade de pointes, ventricular tachycardia) – you may notice sudden dizziness chest pain, palpitation, shortness of breath and become suddenly unconscious.
- pain in the abdomen (stomach area)
- skin lumps or hives (raised, red or white, itchy patches of skin)
- severe kidney problems
- weakness, feeling tired, sleeplessness
- nervousness or agitation
- lack of emotion or indifference to your surroundings (apathy)
- DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) that appears initially as flu-like symptoms and a rash starting on the face and later spreading further over the body with a high temperature and enlarged lymph nodes. The consequences can be life-threatening.
- purpura (purple spots or pinpoint on the skin)

In patients with HIV/AIDS, the following side effects may occur more frequently than in patients without HIV/AIDS:

- allergic reactions
- high levels of potassium in your blood, which can cause abnormal heart beats (palpitations).
- changes in blood tests, including low levels of sodium in your blood and higher blood levels of liver enzymes
- abnormal bruising or bleeding or signs of infection, such as sore throat and high temperature because of low levels of certain blood cells
- excessive breakdown of muscle tissue which can result in muscle pain, dark urine and kidney

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRIMETHOPRIM AND SULFAMETHOXAZOLE TABLETS BP 160 MG/800 MG

Keep out of the reach and sight of children.

Do not use Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of the month.

Do not store above 30°C & Protect from moisture .

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg contains

The active ingredients are sulfamethoxazole and trimethoprim

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

The other ingredients are:

Maize Starch BP

Sodium Lauryl Sulfate BP

Sodium Methyl paraben BP

Sodium Propyl paraben BP

Purified Water BP

Purified Talc BP

Sodium Starch Glycolate (Type-A) BP

What Trimethoprim and Sulfamethoxazole Tablets BP 160 mg/800 mg looks like and content of the pack

A white colour caplet shaped biconvex uncoated tablet having a break line on one side and other side plain of each tablet

Marketing Authorisation Holder and Manufacturer

Manufacturer:

Merit Organics Ltd

Plot No 2104/2/A, G.I.D.C , Sarigam , Bhilad,

Dist- Valsad-396155, Gujarat , INDIA

This medicinal product is authorised in the Member States of the EEA under the following names: NA