WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.[*]

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

[*] https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA598 trade name][†]
Sulfamethoxazole/trimethoprim

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [HA598 trade name] is and what it is used for
2. What you need to know before you take [HA598 trade name]
3. How to take [HA598 trade name]
4. Possible side effects
5. How to store [HA598 trade name]
6. Contents of the pack and other information

1. What [HA598 trade name] is and what it is used for

[HA598 trade name] is used in patients with HIV to prevent or treat certain infections that they can catch. It can be used in:

- infants and children aged under 5 years
- adults and children over 5 years who have severe HIV disease
- patients who have tuberculosis
- patients who live where they can easily catch malaria or other severe infections

[HA598 trade name] can be used to stop you catching:

- a lung infection (pneumonia) caused by an organism called P*neumocystis jirovecii*
- a parasite infection that affects the brain and eyes (toxoplasmosis)
- malaria
- several other infections

The medicine can also be used for treating:

- *Pneumocystis jirovecii* pneumonia
- toxoplasmosis

[HA598 trade name] is a combination of two antibiotics: sulfamethoxazole and trimethoprim. The two substances work together to stop the growth of certain organisms that cause infections.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

2. What you need to know before you take [HA598 trade name]

Do not take [HA598 trade name] 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 [HA598 trade name] (see section 6: Contents of the pack and other information).
- are allergic to sulfonamide medicines, for example sulfonylureas (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 attacks of porphyria, a rare blood problem which can affect your skin or nervous system

Sulfamethoxazole/trimethoprim should not be taken together with some other medicines that may increase the risk of severe side effects. Tell your health care provider about any other medicines you are taking and see under '**Taking other medicines**' below for more advice.:

This medicine should not be given to a child who is less than 4 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 reaction, stop taking this medicine and get urgent advice from a health care provider, telling them that you have been taking this medicine.

Signs of a severe reaction 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 at first as reddish target-like spots or circular patches on your body, often with central blisters. Additional signs to look for are ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These skin rashes are often accompanied by flu-like symptoms. The rash may develop into widespread blistering or peeling of the skin.

Also tell your health care provider right away if you get abnormal bleeding or bruising, persistent cough with difficulty breathing, or if you feel as if you might faint or become pale, cold and sweaty,

Talk to your health care provider before taking [HA598 trade name] if you:

- have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause breakdown of red blood cells and jaundice.
- 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 [HA598 trade name] for a long time, you may need to have regular urine and blood tests and you may be given supplements. 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 [HA598 trade name] can affect the way some medicines work. Also, some other medicines can affect the way [HA598 trade name] works.

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

- thiazides which are medicines (diuretics) that increase the amount of urine you produce
- dapsone, 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
- folinic acid
- contraceptive medicines
- sulfadoxine, pyrimethamine or amodiaquine, medicines used to treat or prevent malaria medicines that stop the bone marrow from working properly and/or decrease the number of blood cells in the body. Examples are:
  - clozapine, a medicine for psychiatric problems
  - 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 CMV (cytomegalovirus) infection
  - pyrimethamine, used to treat malaria or an infection called toxoplasmosis

Taking [HA598 trade name] with food and drink

You can take your medicine with food or between meals. You should also make sure you drink enough fluids (e.g. water, juice or tea) while you are taking this medicine, as it reduces the risk of some side effects.

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

[HA598 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

3. How to take [HA598 trade name]

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

Preventing serious infections in people living with HIV

If you are living with HIV, your health care provider may recommend that you take [HA598 trade name] regularly to **prevent serious infections** such as *Pneumocystis jirovecii* lung infections, infection due to *Toxoplasma* (toxoplasmosis) or malaria, particularly if you live in an area where malaria or severe infections are common.

The dose depends on how much you weigh, as follows:

Body Weight	Dose
6 to less than 15 kg	½ tablet daily
15 to less than 25 kg	1 tablet daily
25 kg and over	2 tablets daily

For patients weighing less than 6 kg, other products that can provide a lower dose of the active substances in this medicine may be used.

Treating serious infections in people living with HIV

If you are living with HIV and get certain other serious infections, your health care provider may prescribe a different dose of [HA598 trade name]. The dose of [HA598 trade name] and how long you need to take it depends on the infection you have and how bad it is.

Your health care provider will work out the dose needed, which is usually based on body weight:

- To treat a lung infection caused by *Pneumocystis jirovecii*, [HA598 trade name] is taken 3 to 4 times daily for 14 to 21 days; your health care provider will work out a suitable number of tablets for each dose.
- To treat toxoplasmosis, the medicine is taken 2 times daily; your health care provider will work out a suitable number of tablets for each dose.

If you have kidney problems, your health care provider may prescribe a lower dose of [HA598 trade name].

If you take more [HA598 trade name] 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 sulfamethoxazole/trimethoprim, you may feel or be sick, feel dizzy or confused.

If you forget to take [HA598 trade name]

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 (are sick) 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 [HA598 trade name].

If you stop taking [HA598 trade name]:

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, [HA598 trade name] can cause side effects, although not everybody gets them.

You may develop a severe reaction to this medicine (as described in Section 2).

Chances of a severe reaction are generally very rare (fewer than 1 in 10 000 people are affected). **Tell your health care provider immediately if you have a severe reaction and do not take any more [HA598 trade name].**

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)

- cough, 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)
- a severe condition of general reddening of the skin with pustules and fever (acute generalised exanthematous pustulosis)
- 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 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.
- Difficulty passing urine, passing more or less urine than usual.
- kidney problems (you may notice tiredness, swelling or puffiness in the face, belly, 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 or hearing things that are not there (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.
- problems with getting enough blood to the organs (shock) which may cause rapid heart rate, cold clammy skin, thirst, confusion and loss of consciousness
- pain in the abdomen (belly)
- 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)
- severe mental problems where you cannot distinguish what is real (psychosis)
- 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 swollen lymph nodes. The reaction can be life-threatening.
- purpura (purple spots or pinpoints on the skin)
- plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweet's syndrome)

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 problems

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [HA598 trade name]

Keep this medicine out of the sight and reach of children.
Do not store above 30°C. Store in the original container.
Do not use this medicine after the expiry date stated on the carton, bottle or blister after "EXP". The expiry date refers to the last day of that month.
Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.
Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

[HA598 trade name] is a white to off-white, flat, circular, bevel-edged, uncoated tablet, with "MICRO" engraved on one side and the other side debossed with "COTRIM", with a break line separating the "480".

The break line can be used to divide [HA598 trade name] into equal doses.

What [HA598 trade name] contains

- The active ingredients are 400 mg of sulfamethoxazole and 80 mg of trimethoprim.

- The other ingredients of [HA598 trade name] are sodium starch glycolate, docusate sodium, sodium benzoate, pregelatinized starch and magnesium stearate.
  There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [HA598 trade name] looks like and contents of the pack

White to off-white, flat, circular, bevel-edged, uncoated tablet, with "MICRO" engraved on one side and the other side debossed with "COTRIM", with a break line separating the "480".

The break line can be used to divide [HA598 trade name] into equal doses.

[HA598 trade name] is available as:

- PVC/PVDC-aluminium blister pack of 10 tablets. 10, 50 or 100 blister packs per carton.

- Plastic (HDPE) bottles of 100s or 500s
  The tablets are packed in a sealed polythene bag, which is packed together with a silica gel sachet in a second sealed polythene bag, which is in turn packed in a white HDPE bottle with an aluminium tagger seal and closed with a screw cap.

- Plastic (HDPE) bottles of 1000s
  The tablets are packed in a sealed polythene bag, which is packed together with 2 silica gel sachets in a second sealed polythene bag, which is in turn packed in a white HDPE bottle with an aluminium tagger seal and closed with a screw cap.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products