

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

[MA117 trade name][†]

Pyrimethamine/sulfadoxine + amodiaquine (hydrochloride)

The warnings and instructions in this leaflet are intended for the person taking the medicine. If you are a parent or carer responsible for giving the medicine to someone else such as a child, you will need to apply the instructions accordingly.

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 [MA117 trade name] is and what it is used for
2. What you need to know before you take [MA117 trade name]
3. How to take [MA117 trade name]
4. Possible side effects
5. How to store [MA117 trade name]
6. Contents of the pack and other information

1. What [MA117 trade name] is and what it is used for

[MA117 trade name] is made of two types of tablets. One type of tablet contains a medicine called amodiaquine whereas the other type contains two medicines: sulfadoxine and pyrimethamine.

[MA117 trade name] is used to prevent malaria in children aged between 1 year and less than 10 years, during the malaria season (usually during the rainy season).

Your health care provider will follow the most recent official guidelines on the use of malaria medicines to select the right medicine for you and decide when you should start taking the medicine.

2. What you need to know before you take [MA117 trade name]

[MA117 trade name], like other medicines used to prevent malaria, may not offer 100% protection against infection. In addition, wearing protective clothing, use of insect repellents and bed nets remain important in malaria prevention. See your health care provider if you have signs of fever.

You must not take [MA117 trade name] if you:

- are allergic (hypersensitive) to amodiaquine, pyrimethamine, sulfadoxine (or another sulphonamide) or to any of the other ingredients of [MA117 trade name] (see section 6)
- have ever suffered blood disorders with amodiaquine, pyrimethamine or sulfadoxine
- have ever had liver problems with amodiaquine
- have an eye problem called retinopathy that affects the light-sensitive layer at the back of the eye

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

- have low levels of red blood cells which can cause tiredness (megaloblastic anaemia)
- are suffering from a recent illness. If you have malaria, then you may need treatment with a different medicine
- have been treated in the past 30 days with medicines containing amodiaquine or pyrimethamine and sulfadoxine
- are HIV-positive and have been taking a combination of sulfamethoxazole and trimethoprim

If you are not sure you should take [MA117 trade name], talk to your health care provider before taking the medicine.

Take special care with [MA117 trade name]

Check with your health care provider before taking [MA117 trade name] if you:

If any of the above apply to you, or if you are not sure, talk to your health care provider before you take [MA117 trade name].

If you get a skin rash or itchiness with [MA117 trade name], stop taking [MA117 trade name] and talk to your health care provider.

Taking other medicines

Tell your health care provider if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

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

- malaria medicines containing amodiaquine, pyrimethamine or sulfadoxine
- medicines containing sulfamethoxazole and trimethoprim (for preventing certain infections in people who are HIV positive)
- HIV medicines containing ritonavir, saquinavir or lopinavir
- antibacterial medicine which contains a sulfonamide
- ketoconazole- an antifungal medicine
- montelukast - a medicine used in asthma
- gemfibrozil - a medicine used to reduce cholesterol and fats in the blood
- anti-depressants
- antipsychotic drugs
- beta blockers (medicines for treating certain heart conditions)

Pregnancy and breastfeeding

If you are pregnant, you must check with your health care provider before you take this medicine, particularly during the first 3 months of pregnancy. If you learn that you are pregnant during the treatment, speak with your health care provider. You can breastfeed your baby during treatment with this medicine but check with your health care provider first.

Driving and using machines

If you feel dizzy or tired after taking this medicine, you should not drive or operate machinery.

3. How to take [MA117 trade name]

Your health care provider will tell you when to start treatment with [MA117 trade name].

To get the best protection you will be given 3 to 5 courses of [MA117 trade name] during the malaria season. Each course lasts 3 days and you will take the medicines in the presence of the health care provider on the first day. There should be a gap of 28 days between the courses.

The doses recommended below are suitable for patients aged 1 year to 10 years.

Dose (patient aged 1 year – less than 5 years)		
	Amodiaquine tablet (153 mg)	Sulfadoxine/Pyrimethamine tablet (500 mg/25 mg)
Day 1	1 tablet as a single dose	1 tablet as a single dose
Day 2	1 tablet as a single dose	–
Day 3	1 tablet as a single dose	–

Take 1 yellow tablet (amodiaquine 150 mg) and 1 white tablet (sulfadoxine/pyrimethamine 500 mg/25 mg) on day 1, then 1 yellow tablet on day 2 and finally 1 yellow tablet on day 3.

Dose (patient aged 5 years – 10 years)		
	Amodiaquine tablet (153 mg)	Sulfadoxine/Pyrimethamine tablet (500 mg/25 mg)
Day 1	2 tablets as a single dose	2 tablets as a single dose
Day 2	2 tablets as a single dose	–
Day 3	2 tablets as a single dose	–

Take 2 yellow tablets (amodiaquine 150 mg) and 2 white tablets (sulfadoxine/pyrimethamine 500 mg/25 mg) on day 1, then 2 yellow tablets on day 2 and finally 2 yellow tablets on day 3.

Instructions on how to take the tablets

The tablets should not be broken.

The tablets should be dispersed in water.

For taking [MA117 trade name] on the **first day of treatment**, you need 2 clean cups or glasses:

- **For children aged 1 to 5 years**, add approximately 10 mL of drinking water into each cup/glass;
 - Place 1 amodiaquine dispersible tablet into one cup/glass, and 1 sulfadoxine/pyrimethamine dispersible tablet into the other cup/glass;
- **For children aged 5 to 10 years**, add approximately 20 mL of drinking water into each cup/glass;
 - Place 2 amodiaquine dispersible tablets into one cup/glass, and 2 sulfadoxine/pyrimethamine dispersible tablets into the other cup/glass;
- Let the tablets disperse, then shake thoroughly the mixtures obtained and immediately drink the contents of the two cups/glasses;
- Rinse the two cups/glasses with additional approximately 10 mL of drinking water and drink the contents to ensure that you take the whole dose.

For taking [MA117 trade name] on the **second and third day of treatment**, you only need one clean cup or glass:

- **For children aged 1 to 5 years**, add approximately 10 mL of drinking water into the cup/glass;
 - Place 1 amodiaquine dispersible tablet into the cup/glass;
- **For children aged 5 to 10 years**, add approximately 20 mL of drinking water into the cup/glass;
 - Place 2 amodiaquine dispersible tablets into the cup/glass;

- Let the tablets disperse, then shake thoroughly the mixtures obtained and immediately drink the contents of the cup/glass;
- Rinse the cup/glass with additional approximately 10 mL of drinking water and drink the contents to ensure that you take the whole dose.

If you vomit within 30 minutes of taking the tablet, then you will need to take another tablet. Wait for 10 minutes before taking the replacement dose.

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

If you take more [MA117 trade name] than you should

If you take too much [MA117 trade name], tell your health care provider.

If you do not take [MA117 trade name] at the right time

You should take the medicines at the right time to have the best chance of preventing malaria. If you miss a dose, take the missed dose as soon as you can and take the next one after at least 8 hours. If you miss a full course (a month after the previous one) then you will be less protected but you should still receive the next course.

4. Possible side effects

Like all medicines, this medicine can cause side effects but not everybody gets them.

The most common side effects of amodiaquine are vomiting, stomach pain, fever, diarrhoea, itching, headaches and rash. Pyrimethamine/sulfadoxine can cause skin rash and side effects on moist areas such as the lining of the nose and the mouth.

Serious but rare side effects include blood disorder, liver damage and severe skin reactions.

Other side effects have occurred with amodiaquine and pyrimethamine/sulfadoxine usually in adults treated for malaria but not when these medicines are used for seasonal malaria prevention in children. These side effects include:

Mental and nervous system disorders:

Depression, nervousness, apathy, dizziness, nerve disorders, fits, inability to move properly, sleeplessness, muscle weakness, hallucinations

Digestive system

Loss of appetite, feeling sick, inflammation of the tongue and in the mouth, stomach feeling full

Liver and pancreas

Inflammation of the pancreas and blood test showing a temporary increase in liver enzymes

Skin

Skin reactions caused by sunlight, slight hair loss, grey coloration of the skin and the lining of the nose and mouth

Eyes

Temporary problems with focussing, clouding of the clear layer at the front of the eye (which gets better when the medicine is stopped), damage to the light-sensitive layer at the back of the eye, swelling around the eyes, and redness

Ear

Ringling or buzzing sound in the ear, sense of losing balance or feeling giddy

Heart

Inflammation of the heart and of the sac that surrounds the heart

Blood and kidney disorders

Kidney disorders, reduced urine, kidney stones. Sulfadoxine can increase urine volume

Reduced quantity of white blood cells, red blood cells and platelets

Clotting disorder, increased quantity of white blood cells and blood spot under the skin.

Allergic reactions

Allergic reactions including skin rashes, joint stiffness and fever, swelling of the throat, face, and other parts of the body

Bones

Joint pain

Lungs

Allergic reactions in the lungs

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 [MA117 trade name]

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

Do not store above 30°C, store the tablets in blisters in the provided box/carton. Protect from light.

Do not use this medicine after the expiry date stated on the blister and carton after “EXP”.

Do not use this medicine if you notice description of the visible signs of deterioration 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

What [MA117 trade name] contains

- [MA117 trade name] consists of amodiaquine (as hydrochloride) 153 mg dispersible tablets and pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets, co-blistered.
- The active ingredient of amodiaquine (as hydrochloride) 153 mg dispersible tablet is amodiaquine (as hydrochloride).
- The active ingredients of pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablet are pyrimethamine and sulfadoxine.
- The other ingredients of amodiaquine (as hydrochloride) 153 mg dispersible tablet are povidone, sodium bicarbonate, microcrystalline cellulose, crosslinking carboxymethyl cellulose sodium, sucralose and magnesium stearate
- The other ingredients of pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablet are hypromellose, low-substituted hydroxypropyl cellulose, sucralose 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 [MA117 trade name] looks like and contents of the pack

Amodiaquine (as hydrochloride) 153 mg dispersible tablets

Yellow, round, uncoated tablets. They are flat on the top and bottom with a bevelled edge. The tablets have 'AQ' debossed (stamped into) on one side and a score line on the other side.

Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablets

White, round, uncoated tablets. They are flat on the top and bottom with a bevelled edge. The tablets have 'SP' debossed (stamped into) on one side and a score line on the other side.

The tablets are packaged in colourless transparent plastic (PVC) on aluminium foil blister cards, each containing three Amodiaquine (as hydrochloride) 153 mg dispersible tablets and one Pyrimethamine/Sulfadoxine 25mg/500mg dispersible tablet. Available in box of 50 x 4 co-blisters. Such 60 boxes packed in larger carton.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact 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>