

## 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.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

[MA170 trade name]<sup>†</sup>  
Amodiaquine (hydrochloride)+pyrimethamine/sulfadoxine

*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 [MA170 trade name] is and what it is used for
2. What you need to know before you take [MA170 trade name]
3. How to take [MA170 trade name]
4. Possible side effects
5. How to store [MA170 trade name]
6. Contents of the pack and other information

#### 1. What [MA170 trade name] is and what it is used for

[MA170 trade name] is made of two types of tablets. One type of tablet contains a medicine called amodiaquine and the other contains two medicines: sulfadoxine and pyrimethamine.

[MA170 trade name] is used to prevent malaria in infants, 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 [MA170 trade name]

[MA170 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 [MA170 trade name] if you:**

- are allergic (hypersensitive) to amodiaquine, pyrimethamine, sulfadoxine (or another sulphonamide) or to any of the other ingredients of [MA170 trade name] (see section 6)
- have ever suffered blood disorders with amodiaquine, pyrimethamine or sulfadoxine
- have ever had liver problems with amodiaquine

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- have an eye problem called retinopathy that affects the light-sensitive layer at the back of the eye
- 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 4 weeks 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 [MA170 trade name], talk to your health care provider before taking the medicine.

### **Take special care with [MA170 trade name]**

Check with your health care provider before taking [MA170 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 [MA170 trade name].

If you get a skin rash or itchiness with [MA170 trade name], stop taking [MA170 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.

### Other ingredients of [MA170 trade name]

[MA170 trade name] contains aspartame. Aspartame is a source of phenylalanine. It may be harmful in patients with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

[MA170 trade name] also contains small amounts of lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption may experience symptoms of intolerance. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance in other patients.

### 3. How to take [MA170 trade name]

Your health care provider will tell you when to start treatment with [MA170 trade name].

To get the best protection you will be given 3 to 5 courses of [MA170 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 infants aged 3 months to less than 1 year.

	Dose (infant aged 3 months to less than 1 year)	
	Amodiaquine tablet (76.5 mg)	Sulfadoxine/Pyrimethamine tablet (250 mg/12.5 mg)
<b>Day 1</b>	1 tablet as a single dose	1 tablet as a single dose
<b>Day 2</b>	1 tablet as a single dose	–
<b>Day 3</b>	1 tablet as a single dose	–

*Take 1 yellow tablet (amodiaquine 76.5 mg) and 1 white tablet (sulfadoxine/pyrimethamine 250 mg/12.5 mg) on day 1, then 1 yellow tablet on day 2 and finally 1 yellow tablet on day 3*

This product does not provide adequate protection for children 1 year old or more – your health care provider will recommend a more suitable medicine in older children.

#### ***Instructions on how to take the tablets***

The tablets should be dispersed (made into a mixture) in water.

For taking [MA170 trade name], you need a clean cup or glass.

#### **On the first day of treatment:**

- Add about 10 mL of drinking water into the cup/glass;
- Put the yellow amodiaquine tablet and the white sulfadoxine/pyrimethamine tablet into the water in the cup/glass;
- Let the tablets disperse, then gently but thoroughly shake the mixture (being careful not to spill any) and let the infant drink the contents of the cup/glass right away;
- Rinse the cup/glass with another 10 mL or so of drinking water and let the infant drink the contents to ensure that the whole dose is taken.

**On the second and third day of treatment:** Add about 10 mL of drinking water into the cup/glass;

- Put the yellow amodiaquine tablet into the water in the cup/glass;
- Let the tablet disperse, then gently but thoroughly shake the mixture (being careful not to spill any) and let the infant drink the contents of the cup/glass right away;
- Rinse the cup/glass with another 10 mL or so of drinking water and let the infant drink the contents to ensure that the whole dose is taken.

**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 take more [MA170 trade name] than you should**

If you take too much [MA170 trade name], tell your health care provider.

**If you do not take [MA170 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.

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

**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*

Ringing 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 [MA170 trade name]**

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

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

Do not use this medicine after the expiry date stated on the blister or carton 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**

#### **What [MA170 trade name] contains**

- The active ingredient of the yellow tablet is amodiaquine (as hydrochloride) 76.5 mg and the active ingredients of the white tablet are pyrimethamine 12.5 mg and sulfadoxine 250 mg.
- The other ingredients of [MA170 trade name] are:

#### *Yellow tablet (amodiaquine [as hydrochloride] 76.5 mg dispersible tablet)*

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, basic butylated methacrylate copolymer, aspartame, orange flavour, sodium bicarbonate and sodium stearyl fumarate.

#### *White tablet (pyrimethamine / sulfadoxine 12.5 mg/250 mg dispersible tablet)*

pregelatinized starch, croscarmellose sodium, colloidal silicon dioxide, microcrystalline cellulose, aspartame, orange flavour and sodium stearyl fumarate.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

#### **What [MA170 trade name] looks like and contents of the pack**

##### *Amodiaquine (as hydrochloride) 76.5 mg dispersible tablets*

Yellow, round, flat, bevelled edge, uncoated tablet debossed with ‘J 11’ on one side and plain on other side. The score line is not intended for breaking the tablet.

Amodiaquine (as hydrochloride) +  
pyrimethamine/sulfadoxine  
76.5mg+12.5mg/250mg dispersible tablets  
(Macleods Pharmaceuticals Ltd), MA170

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*Pyrimethamine/sulfadoxine 12.5mg/250 mg dispersible tablets*

White to off white, round, flat-faced, bevelled edge, uncoated tablet, debossed with 'F' and '42' on either side of score line on one side and plain on other side.

The score line is not intended for breaking the tablet.

[MA170 trade name] is available as clear PVC/PVDC-Alu blister card, containing three (3) tablets of amodiaquine (as hydrochloride) 76.5 mg and one (1) tablet of pyrimethamine/sulfadoxine 12.5 mg/250 mg. Pack size: 50 blister cards per carton.

**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>