

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

[MA133 trade name][†]
Amodiaquine (hydrochloride)/artesunate

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 [MA133 trade name] is and what it is used for
2. What you need to know before you take [MA133 trade name]
3. How to take [MA133 trade name]
4. Possible side effects
5. How to store [MA133 trade name]
6. Contents of the pack and other information

1. What [MA133 trade name] is and what it is used for

[MA133 trade name] is a medicine used to treat malaria. It contains two active substances, artesunate and amodiaquine, which work together to kill the malaria parasite.

Malaria is caused by infection with a parasite, spread by the bite of an infected mosquito. [MA133 trade name] is normally used when the malaria is caused by a type of malaria parasite called *Plasmodium falciparum*. It can be used only when the infection is not severe enough to affect the brain or other key organs.

[MA133 trade name] may sometimes also be given to everybody in an area to reduce the spread of malaria. Your health care provider will explain to you if this is the case.

Your health care provider will follow the most recent official guidelines on the use of malaria medicines to select the right medicine for your malaria treatment.

2. What you need to know before you take [MA133 trade name]

Do not take [MA133 trade name]

- if you are allergic to artesunate, amodiaquine or to any of the other ingredients of [MA133 trade name] (see section 6, What [MA133 trade name] contains);
- if you have ever had liver problems (see below) during treatment with amodiaquine;
- if you have ever been told you had low white blood cell counts (especially if you had symptoms such as sudden high fevers with sore throat or ulcers in the mouth) during treatment with amodiaquine;
- if you have an eye disease with damage to your retina.

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

If you have any doubt, check with your health care provider.

Take special care with [MA133 trade name]

This medicine may rarely damage the liver or cause blood problems that can be serious. Tell your health care provider before starting treatment if you have problems with your liver or kidneys, or any blood disorder, including sickle cell disease or thalassaemia. Also tell your health care provider if you have previously been advised that you have a condition called glucose-6-phosphate dehydrogenase (G6PD) deficiency, which may make you sensitive to certain medicines.

Stop treatment with [MA133 trade name] and speak with your health care provider straightaway if you:

- lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash

and you have any of the following

- belly pain, usually on the right side and near the chest
- unexplained itching
- yellowing of the white parts of your eyes, your nails or your skin
- passing dark urine
- passing stools that are very pale

These are signs of a problem with your liver, which can become serious.

You should also stop treatment and contact your health care provider straightaway if you get high fever, sore throat or mouth ulcers, which may be signs of blood problems.

This medicine may sometimes affect the activity of your heart. Tell your health care provider if:

- you have ever had heart problems, especially a problem with your heart rhythm or a slow heartbeat;
- a close relative has had heart rhythm problems or died suddenly;
- you have low levels of potassium or magnesium in your blood.

Tell your health care provider if you have used this or another amodiaquine-containing medicine very recently. This is because you are more likely to get side effects.

This medicine may cause abnormal movements of the head, tongue or neck (extrapyramidal symptoms, see section 4, Possible side effects). These symptoms usually disappear when you stop the treatment. If these rare effects occur, stop the treatment and speak with your health care provider immediately. You may need other treatment for these symptoms. Your doctor may recommend another malaria treatment.

If in doubt, always ask your health care provider.

Taking other medicines

It is important to tell your health care provider if you have been taking or are planning to take any other medicines, including medicines obtained without a prescription. Some medicines and [MA133 trade name] interfere with each other, or may increase the risk of side effects.

Some of these medicines include:

- efavirenz, lopinavir, nevirapine, ritonavir, saquinavir – medicines used to treat HIV
- gemfibrozil – to treat high cholesterol or excess fat in the blood
- ketoconazole – for fungal infections
- methoxsalen – for skin diseases
- montelukast – for asthma
- pilocarpine – a medicine for eye problems or dry mouth
- tranylcypromine – a medicine for depression
- trimethoprim – for infections.

Pregnancy and breast-feeding

Tell your health care provider if you are pregnant, think you may be pregnant or if you become pregnant while taking the medicine.

[MA133 trade name] is one of several malaria treatments that can be used in pregnancy – your health care provider will select the most appropriate malaria medicine for your situation. If you are given [MA133 trade name] while pregnant, your health care provider may carry out extra checks on how your pregnancy progresses.

You may breast-feed your baby while taking this medicine, but tell your health care provider if you are breast feeding.

Driving and using machines

Patients receiving [MA133 trade name] should be warned that somnolence, dizziness or asthenia may occur, in which case they should not drive or use machines.

Important information about some of the ingredients of [MA133 trade name]

[MA133 trade name] contains mannitol which may have a mild laxative effect.

3. How to take [MA133 trade name]

Always take [MA133 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

The dose depends on the weight of the person taking the medicine. The usual dose is:

Weight	Dose
9 kg to less than 18 kg	1 tablet [MA133 trade name] daily for 3 days
18 kg to 36 kg	2 tablets [MA133 trade name] daily for 3 days
more than 36 kg	4 tablets [MA133 trade name] daily for 3 days

Do not take [MA133 trade name] with a meal that contains a high amount of fat.

Swallow the tablet with a drink of water.

For a person who cannot swallow the tablets whole, the tablets can be crushed and swallowed with water, or mixed with water and swallowing the mixture.

If you vomit within half-an-hour of taking the tablets, take another dose as soon as you can. Then contact your health care provider for more tablets to finish the course. Tell your health care provider if you keep vomiting.

If you take more [MA133 trade name]

If you accidentally take too many tablets, then you or somebody else should immediately contact a health care provider or the nearest hospital emergency department. An overdose of this medicine can cause headaches, dizziness, visual disturbances, a drop in blood pressure, convulsions (seizures or fits), or abnormal movements of the head, tongue or neck. If any of these symptoms occur, see a health care provider immediately.

If you forget to take [MA133 trade name]

Make sure that you do not miss a dose of this medicine. However, if you forget a dose, take the missed dose as soon as you remember. Take the next dose as usual. Do not take a double dose to make up for a forgotten tablet.

If you stop taking [MA133 trade name]

For this medicine to work properly you must take it regularly until you finish the course. Even if you feel better, it does not mean that your malaria has been completely cured. Tiredness, nausea and vomiting may be caused by the infection and not by the medicine so you should not stop your medicine if you get these effects.

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

4. Possible side effects

Like all medicines, [MA133 trade name] can cause side effects, although not everybody gets them.

Common side effects (affects 1 to 10 users in 100): loss of appetite, difficulty sleeping, sleepiness, cough, nausea, belly pain, weakness, sleepiness, alteration of the activity of the heart (called ‘prolongation of QT interval’).

Uncommon side effects (affects 1 to 10 users in 1000): acute bronchitis, gastroenteritis, oral thrush, decrease in red blood cell count (anaemia), low blood sugar, hallucination (seeing, hearing or feeling things that are not there), tingling and numbness of the limbs, yellowing of the white of the eye, dizziness, heart rhythm disorders, slow heart rate, diarrhoea, vomiting, itching, rashes, swelling of the face, skin disorders, joint pain, swelling of the limbs (oedema), fever.

Rare side effects (affect 1 to 10 users in 10 000): damage to nerves and muscles (neuromyopathy)

Very rare side effects (affecting less than 1 in 10 000 users): damage to the retina (the back of the eye) affecting vision

Other side effects reported whose frequency has not been established: allergy, low number of white blood cells (which can make you more prone to infections), nervous system disorders called extrapyramidal disorders (including spasms or abnormal movements of the tongue, face and head, and difficulty speaking or moving normally), headache, fits (convulsions), difficulty focusing vision, clouding of the clear layer over the eye, potentially severe disturbances of liver function, enlarged spleen, yellowing of the skin and eyes, slate-grey coloration of the skin (especially of the fingers), and mucous membranes (lining of body cavities), cold, flu, rhinitis (runny nose), shivering, and sore throat.

Some of these effects may be caused by the malaria.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, tell your health care provider.

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 [MA133 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.

Do not use this medicine after the expiry date stated on the label and carton after {EXP}. The expiry date refers to the last day of that month.

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 [MA133 trade name] contains

- The active ingredients are amodiaquine and artesunate.
- The other ingredients of [MA133 trade name] are mannitol, hydroxypropylcellulose, colloidal anhydrous silica, magnesium stearate, pregelatinized starch, croscarmellose sodium, polysorbate 80.

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

What [MA133 trade name] looks like and contents of the pack

[MA133 trade name] is a capsule-shaped, uncoated tablets, yellow on one side and white to slightly yellow on the other side. They are biconvex (rounded on top and bottom) with flat edges. The tablets have 'AA' and '50' debossed (stamped into), separated by a break line, on the white to slightly yellowish side of the tablet and are plain of the yellow side.

The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/EVOH-Aclar blister pack

Clear colourless plastic (PVC/EVOH/Aclar) on aluminium foil blister cards, each containing 3 tablets. Available in boxes of 1×3, 10×3 or 25×3 tablets.

Aluminium–Aluminium blister pack

Aluminium foil on aluminium foil blister cards, each containing 3 tablets.

Available in boxes of 1×3, 10×3 or 25×3 tablets.

Supplier and Manufacturer

Supplier

Micro Labs Limited
#31, Race Course Road
Bengaluru -560001
India
Tel.:+91(0)80-22370451 to 57
Fax.:+91(0)80-22370463
E-mail.:info@microlabs.in

Manufacturer

Micro Labs Limited
Plot No S-155 to S-159 & N1
Phase-III and Phase IV
Verna industrial estate, Verna
Goa – 403722,
India
Tel.:+91(0)832-6686262
Fax.:+91(0)832-6686203
E-mail.:jainethesh@microlabs.in

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>