

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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[MA058 trade name][†]

Artesunate/Amodiaquine hydrochloride

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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem 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 [MA058 trade name] is and what it is used for
2. What you need to know before you take [MA058 trade name]
3. How to take [MA058 trade name]
4. Possible side effects
5. How to store [MA058 trade name]
6. Contents of the pack and other information

1. What [MA058 trade name] is and what it is used for

[MA058 trade name] is used to treat malaria. It contains two antimalarial medicines, artesunate and amodiaquine, which work together to kill the malaria parasite in your body. Your health care provider has recommended [MA058 trade name] for you because you have malaria.

It is to be used only for treating uncomplicated malaria caused by *Plasmodium falciparum* (a type of malaria parasite). Uncomplicated malaria is when the patient is conscious and is not suffering serious symptoms such as severe anaemia, jaundice, breathing difficulties and kidney failure. For complete cure it is important that you finish taking all the tablets that your health care provider has prescribed for you.

2. What you need to know before you take [MA058 trade name]

Do not take [MA058 trade name]

- if you are allergic to artesunate, amodiaquine or to any of the other ingredients of [MA058 trade name] (see section 6, What [MA058 trade name] contains);
- if you have ever had liver problems during treatment with amodiaquine;
- if you have ever suffered from sudden high fevers, shaking, severe sore throat or ulcers in the mouth (symptoms of low white blood cell count) during treatment with amodiaquine;
- if you have an eye disease with damage to your retina.

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

Take special care with [MA058 trade name]

This medicine may rarely damage the liver or cause blood problems that can be fatal. If you feel weak, have nausea, vomiting, abdominal pain, jaundice (yellowing of the skin with dark urine, pale bowel motions), sore throat or mouth ulcers, stop treatment with [MA058 trade name] and see your health care provider immediately; you may need blood tests.

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.

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

This medicine may cause abnormal movements of the head, tongue or neck (extrapyramidal symptoms, see section 4, Possible side effects). These symptoms are usually reversed by discontinuation of 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.

Tell your health care provider if:

- you have ever had a problem with your heart rhythm or any other heart problem;
- a close relative has had heart rhythm problem or died suddenly;
- you have low levels of potassium or magnesium in your blood;
- you have problems with your liver or kidneys.

If in doubt, ask your health care provider.

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. Some medicines and [MA058 trade name] interfere with each other. Some of these medicines include:

- other medicines used to treat malaria,
- medicines used to treat an abnormal heart rhythm,
- medicines that can have side effects on your heart, including some medicines used to treat depression or mental illnesses, and some antibiotic medicines,
- medicines used to treat HIV/AIDS.

Pregnancy and breast-feeding

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 breast-feed 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 [MA058 trade name]

Always take [MA058 trade name] exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

The dose depends on the patient's weight as follows:

Weight (approximate age)	Dose
18 kg to 36 kg (6 to 13 years)	1 tablet [MA058 trade name] daily for 3 days (100 mg artesunate + 270 mg amodiaquine daily for 3 days)
more than 36 kg (over 14 years)	2 tablets [MA058 trade name] daily for 3 days (200 mg artesunate + 540 mg amodiaquine daily for 3 days)

Do not take [MA058 trade name] with a meal that contains a high amount of fat.

Swallow the tablet with a drink of water.

For very young children or patients 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 [MA058 trade name]

If you accidentally take a lot more 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 (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 [MA058 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 [MA058 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, [MA058 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, abdominal pain, weakness, tiredness.

Uncommon side effects (affects 1 to 10 users in 1,000): acute bronchitis, gastroenteritis, oral thrush, decrease in red blood cell count (anaemia), hypoglycaemia (low blood sugar), hallucination, tingling and numbness of the limbs, yellowing of the eye, dizziness, heart rhythm disorders, diarrhoea, vomiting, itching, rashes, swelling of the face, skin disorders, joint pain, swelling of the limbs (oedema), fever.

During post-marketing experience the following additional side effects have been reported: Common side effects (affects 1 to 10 users in 100): alteration of the heart rhythm (called 'prolongation of QT interval').

Frequency not known: low number of white blood cells (which can make you more prone to infections), potentially severe disturbances of liver function, eye disorders, slate-grey pigmentation, especially of the fingers and mucous membranes (lining of body cavities), nervous system problems and muscle impairment. Headache, cold, flu, rhinitis (runny nose), shivering, sore throat, swelling of the spleen, convulsion (fits), yellowing of the skin, allergic reaction. Some of these effects may be caused by the malaria.

Also, side effects called extrapyramidal symptoms can occur. These symptoms include abnormal movements of the head, tongue or neck (e.g. facial spasms, tongue protrusion, difficulties in speaking) and rigidity in the body, even after a single dose.

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 any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

5. How to store [MA058 trade name]

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

Store this medicine in its original package below 30°C.

Do not use this medicine after the expiry date stated on the blister and outer packaging after EXP. The expiry date refers to the last day of that month.

The tablets may be mottled but it does not alter the safety and effectiveness of the product.

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 [MA058 trade name] contains

- The active ingredients are artesunate and amodiaquine (as hydrochloride).
- The other ingredients of [MA058 trade name] are excipients:
Croscarmellose sodium, Povidone K30, Silicia colloidal anhydrous, Microcrystalline cellulose,
Magnesium stearate and Calcium carbonate DC CS90 (calcium carbonate and maize starch).

What [MA058 trade name] looks like and contents of the pack

[MA058 trade name] is a round bilayer tablet, with score line: one layer is yellow coloured, the other one is white to slightly yellow.

[MA058 trade name] is engraved on one side "AS" and on the other side "100".

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

[MA058 trade name] is presented in:

- Carton box of 1 blister pack of 3 tablets.
- Carton box of 25 blister packs of 3 tablets each.
- Carton box of 1 blister pack of 6 tablets.
- Carton box of 25 blister packs of 6 tablets each.

Supplier and Manufacturer

Supplier

Sanofi
82, Avenue Raspail
94250 Gentilly – France
Tel : +33 (0)1 41 24 70 00

Manufacturer

Maphar,
Boulevard ALKIMIA N°6
Quartier industriel Sidi Bernoussi
20250 Casablanca
Morocco

Sanofi-aventis Maroc,
Route de Rabat R.P.1-
BP2611- Aïn Sebaâ
20250 Casablanca
Morocco
(for batch release)

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

This leaflet was last revised in October 2021

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>