

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

[MA079 trade name][†]
Artesunate/mefloquine

*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 [MA079 trade name] is and what it is used for
2. What you need to know before you take [MA079 trade name]
3. How to take [MA079 trade name]
4. Possible side effects
5. How to store [MA079 trade name]
6. Contents of the pack and other information

1. What [MA079 trade name] is and what it is used for

[MA079 trade name] is a medicine used to treat malaria in adults and children. It contains two active substances, artesunate and mefloquine, which work together to kill the malaria parasite.

Malaria is caused by infection with a parasite called *Plasmodium*, spread by the bite of an infected mosquito. [MA079 trade name] is used only when the infection is not severe enough to affect the brain or other key organs.

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 [MA079 trade name]

Do not take [MA079 trade name]:

- if you are allergic (hypersensitive) to artesunate, mefloquine, or any of the other ingredients of this medicine (listed at the end of this leaflet). If you think you may be allergic, ask your health care provider for advice.
- if your health care provider tells you that you have severe malaria (affecting the brain or with complications affecting other organs such as lungs or kidneys).
- if you have severe liver problems

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

[#] Formerly known as Cipla Limited

- if you have previously experienced blackwater fever (a complication of malaria that affects the blood and kidneys)
- if you are taking certain medicines (see “Other medicines and [MA079 trade name]”).

If any of these apply to you, **tell your health care provider before taking [MA079 trade name]**.

Warnings and precautions

Talk to your health care provider **before taking [MA079 trade name]** if you have:

- epilepsy
- fits (seizures or convulsions)
- heart problems, especially changes in heart rhythm
- liver or kidney problems
- eye problems (e.g. loss of fine detail, colours seem faded, sudden loss of vision, poor vision at night)
- blood or lymphatic disorder (abnormal blood test showing a decrease or an increase in white blood cells, a decrease in red blood cells or platelets)
- neuropathy with signs of e.g. pins and needles, weakness, numbness, new or worsening clumsiness or unsteadiness on your feet, or shaking of the hands and fingers
- inflammation of the lungs, also known as pneumonitis. This is a serious, potentially life-threatening allergic reaction in the lungs which may cause fever, chills, cough, shortness of breath or chest pain.
- experienced a mild to serious potential life threatening allergic reaction to [MA079 trade name] or any of its ingredients
- low blood glucose due to a pre-existing condition called congenital hyperinsulinemic hypoglycaemia
- depression, thoughts about suicide and self-endangering behaviour
- any other mental problem, including anxiety disorder, schizophrenia or psychosis (losing touch with reality)

Take special care with [MA079 trade name]

[MA079 trade name] may cause serious mental problems in some people. Tell your doctor immediately if you experience any of the following while taking [MA079 trade name]:

- suicidal thoughts
- self-endangering behaviour
- severe anxiety
- feelings of mistrust towards others (paranoia)
- seeing or hearing things that are not there (hallucinations)
- nightmares / abnormal dreams
- insomnia
- depression
- feeling restless
- unusual behaviour

Other medicines and [MA079 trade name]

It is important that you tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of [MA079 trade name], or [MA079 trade name] may affect their action. Side effects of either medicine may become worse and/or the medicines may become less effective.

Especially tell your health care provider if you take or have recently taken:

- halofantrine, or you have been prescribed a course of halofantrine. [MA079 trade name] should not be taken within 15 weeks of taking halofantrine.
- medicines such as quinine, quinidine, or chloroquine, used to treat or to prevent malaria.
- medicines for any heart trouble, or high blood pressure, such as β -blocking agents, calcium channel blockers.
- antihistamines for allergies

- medicines for some mental problems (psychiatric disorders). Anti-depressants such as tricyclic anti-depressants, selective serotonin reuptake inhibitors (SSRIs), bupropion or anti-psychotics such as phenothiazines.
- medicines used to treat epilepsy, such as sodium valproate, carbamazepine, phenobarbital, phenytoin
- ketoconazole (used to treat fungal infections) – you should also ask your doctor for advice before taking ketoconazole
- antibiotics used to treat bacterial infections for example rifampicin, penicillins, cephalosporins
- efavirenz (used to treat HIV infections)
- tramadol (used to treat severe pain)
- daclatasvir and ombitasvir/paritaprevir/ritonavir (used for hepatitis C)
- diclofenac (used for pain and inflammation)
- axitinib, vandetanib or imatinib (used to treat cancer)

[MA079 trade name] with food and drink

[MA079 trade name] should be taken after a meal with plenty of liquid.

Pregnancy, breast-feeding and fertility

Pregnancy

[MA079 trade name] can be used during pregnancy. [MA079 trade name] can be used during the second and third trimester of pregnancy. [MA079 trade name] may be used during the first trimester of pregnancy when the first-line option (artemether-lumefantrine) is not suitable or available.

Breast-feeding

The amounts of the active substances of [MA079 trade name] that pass into breast milk are low and [MA079 trade name] can be used during breast-feeding.

Fertility

There is no information on the effects of [MA079 trade name] on fertility in humans.

Driving and using machines

[MA079 trade name] may cause dizziness and tiredness. If you feel dizzy or tired while taking [MA079 trade name], do not drive and do not use any tools or machines.

Driving and using machines

[MA079 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 [MA079 trade name]

Always take [MA079 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 your weight as shown below.

Patient body weight	Dose
Less than 18 kg	Another medicine containing lower amounts of the active substances should be used
18 to less than 30 kg	1 tablet once daily for 3 days
30 kg or more	2 tablets once daily for 3 days

You should take the medicine for 3 days, with no breaks in between:

- Take the first dose immediately when your health care provider has diagnosed malaria.
- Then take the remaining doses at the same time for the next 2 days.

- If you vomit within 30 minutes of taking the medication, you should repeat the dose.

[MA079 trade name] should be taken after a meal with plenty of liquid. If you are not able to swallow the tablets whole, the tablets may be crushed and added to a small amount of soft food or liquid, all of which should be consumed immediately.

If you are unable to tolerate food, [MA079 trade name] should still be taken, but your body may take up less of the medicine.

You should always take [MA079 trade name] exactly as described by the health care provider and it is important to complete the course of tablets that is recommended. Check with your health care provider if you are not sure.

Please inform your health care provider if you took [MA079 trade name] within the last 60 days. In this case a different medicine will be given to you. Repeating a course of [MA079 trade name] within 60 days is not recommended due to increased risk of serious mental problems.

If you take more [MA079 trade name] than you should

If you take too many tablets, immediately contact your health care provider or the nearest hospital emergency department for further advice. Bring the medicine box with you, so that you can easily describe what you have taken.

If you forget to take [MA079 trade name]

Try to make sure that you do not miss any dose. However, if you do forget a dose, take the missed dose as soon as you realise that you have forgotten it. Then take the next dose after the prescribed interval. Do not take a double dose to make up for a forgotten tablet. **Make sure you take all three doses of this regimen.**

If you stop taking [MA079 trade name]

You should keep taking the medicine for as long as your health care provider has ordered, even if you are feeling better. If you stop the medicine too soon, the infection may not be completely cured.

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

4. Possible side effects

Like all medicines, [MA079 trade name] can cause side effects, although not everybody gets them. It is important that you inform the health care provider of any change in your health. However, some side effects could be serious and need immediate medical attention.

If you develop any of the following potentially serious symptoms, you should STOP taking this medicine and also consult a health care provider immediately.

- a mild to serious potential life-threatening allergic reaction (anaphylaxis) to [MA079 trade name] or any of its ingredients with symptoms such as difficulty in breathing, swollen tongue, itching and severe rash
- severe changes in texture and appearance of the skin, especially serious blistering and peeling that affects the mouth, eyes and genitals (Stevens Johnson syndrome)
- fits (seizures or convulsions)
- heart problems e.g. severe changes in heartbeat, including pounding, racing or skipped beats (palpitations)
- inflammation of the lungs, also known as pneumonitis. This is a serious, potentially life-threatening allergic reaction in the lungs which may cause fever, chills, cough, shortness of breath or chest pain.
- severe liver problems which might be demonstrated by a transient increase in your liver enzymes shown by blood tests or other symptoms such as tender, firm or possibly enlarged liver, jaundice (yellowing of skin/eyes), dark urine, light coloured stools and generalised itchiness

Most of the other side effects are mild to moderate and generally disappear after a few days to a few weeks after treatment.

Very common side effects (may affect up to 1 in 10 people): (in more than 1 in every 10 patients treated) include:

- sleeping problems (sleepiness, unable to sleep, bad dreams)

Common side effects (may affect up to 1 in 10 people):

- dizziness
- feeling sick
- vomiting
- vertigo
- headache
- inflammation of a vein
- slow heart rate (bradycardia)
- low blood pressure
- fever
- joint and muscle pain
- cough
- irritated or runny nose
- altered taste
- abdominal pain
- diarrhoea
- rise in liver enzymes (may indicate liver damage)
- problems with your vision
- loss of balance (vertigo)
- stomachache (abdominal pain)
- itching
- depression
- anxiety
- increased levels of a substance called bilirubin seen in blood tests
- yellowing of eyes or skin (jaundice)

Uncommon side effects (greater than 1 in every 1000 patients treated but less than 1 in 100) include:

- constipation
- rash
- hot flushes
- tiredness
- lack of appetite

Not known (frequency cannot be estimated from the available data)

- abnormal blood test results showing a decrease or an increase in white blood cells, a decrease in red blood cells or platelets. Symptoms may include painful mouth or throat ulcers, fever, chills, bruises on the skin, nosebleeds, bleeding in the stomach or vaginal bleeding.
- kidney problems, failure or infection, causing impairment, cessation, infection, or blood in the urine. Symptoms may include abnormal blood tests (increased blood creatinine), feeling dehydrated, fatigue, swelling (oedema), shortness of breath, feeling or being sick, loss of appetite, or headache
- decreased appetite
- fainting
- hearing problems or ringing in the ears
- neuropathy with signs of e.g. “pins and needles”, weakness, new or worsening clumsiness or unsteadiness on your feet, or shaking of the hands and fingers
- forgetfulness (sometimes lasting for more than 3 months)
- difficulties in talking
- difficulties with sense of smell and taste, eye movement, facial sensation and expression, hearing, balance, tasting, tongue movement, head-turning, and raising your shoulders
- changes to blood pressure or heart rate
- cataract, dazzled in the evenings or other vision disturbances, blurred vision

- breathlessness
- pancreas problems; symptoms may include stomach pain, nausea, vomiting, changes to blood pressure or heart rates and breathlessness
- indigestion
- sweating
- hair loss
- muscle weakness
- muscle cramps
- oedema
- chest pain
- abnormal electrical activity of the heart
- Mental health effects [suicide, attempted suicide, suicidal thoughts, self-endangering behaviour, losing touch with reality (psychosis), feelings of mistrust towards others (paranoia), panic attacks, unusual behaviour, feeling confused, seeing or hearing things that are not there (hallucinations), aggression, agitation, feeling restless, unusual changes in your mood, disturbance in attention]

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

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 [MA079 trade name]

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

Do not store above 30°C

Do not use this medicine after the expiry date stated on the label 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 [MA079 trade name] contains

- The active ingredients are artesunate and mefloquine (as hydrochloride).
- The other ingredients of [MA079 trade name] are:
 - Tablet core:* Croscarmellose sodium, magnesium stearate and microcrystalline cellulose.
 - Tablet coating:* Indigo carmine aluminium lake (FD & C Blue #2), hypromellose, macrogol, polysorbate 80 and titanium dioxide.

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

What [MA079 trade name] looks like and contents of the pack

[MA079 trade name] are blue, round, smooth, biconvex, film-coated tablets.

The tablets should not be divided.

[MA079 trade name] are packed in an Aluminium-Aluminium blister strip with 3 tablets. A carton having one strip of 3 tablets and a carton having 2 strips of 3 tablets.

Supplier and Manufacturer

Supplier

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For any information about this medicinal product, please contact 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>