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

[MA211 trade name][†]
Artemether/lumefantrine

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 [MA211 trade name] is and what it is used for
2. What you need to know before you take [MA211 trade name]
3. How to take [MA211 trade name]
4. Possible side effects
5. How to store [MA211 trade name]
6. Contents of the pack and other information

1. What [MA211 trade name] is and what it is used for

[MA211 trade name] is a medicine used to treat malaria in adults and children. It contains two active substances, artemether and lumefantrine, 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. [MA211 trade name] is used when the malaria is caused by a type of malaria parasite called *Plasmodium falciparum* and 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 [MA211 trade name]

Do not take [MA211 trade name]:

- if you are allergic (hypersensitive) to artemether, lumefantrine, 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 a heart condition, such as dangerously irregular heartbeats (arrhythmias), an alteration in the electrical activity of the heart called prolonged QT interval, slow heartbeat, or severe heart disease.
- if any member of your family (e.g. parents, grandparents, brothers and sisters) has died suddenly due to a heart rate problem or is known to have been born with heart rate problems.
- if you are taking certain medicines (see “Other medicines and [MA211 trade name]”).

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

- if you have low blood levels of electrolytes such as potassium or magnesium.

If any of these apply to you**, tell your health care provider before taking [MA211 trade name]**.

Warnings and precautions

Talk to your health care provider **before taking [MA211 trade name]**:

- If you have severe liver or kidney problems. Your health care provider may recommend extra tests to monitor your heart and the level of potassium in your blood.

Take special care with [MA211 trade name]:

- If your condition worsens, or if you feel too unwell to eat and drink, contact your health care provider immediately. Your health care provider may want to perform a test called an electrocardiogram (ECG) and check the levels of electrolytes, such as potassium and magnesium in your blood before and during treatment.
- If you are taking or have taken any other medication for the treatment of malaria, talk to your health care provider, because some of these medicines must not be given together with [MA211 trade name].
- [MA211 trade name] is used to treat malaria due to *Plasmodium falciparum*. If you are also infected with another type of malaria parasite, *Plasmodium vivax*, your health care provider will give you another medicine for you to take after completing [MA211 trade name] treatment.

Other medicines and [MA211 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 [MA211 trade name], or [MA211 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:

- Any other medicines to treat or prevent malaria
- Medicines for your heart
- Antipsychotic medicines (for treatment of abnormal condition of the mind)
- Antidepressants (medicines for depression and low mood)
- Antibiotics
- Antihistamines (for treatment of, e.g., allergies)
- Medicines to treat HIV infection
- Medicines to treat hepatitis B or hepatitis C infection
- Medicines against fungal infection
- Hormonal methods of birth control (for example birth control pills or contraceptive patch)

[MA211 trade name] with food and drink

[MA211 trade name] should be taken with food or a milky drink.

Pregnancy, breast-feeding and fertility

Pregnancy

[MA211 trade name] can be used during pregnancy.

Breast-feeding

The amounts of the active substances of [MA211 trade name] that pass into breast milk are low and [MA211 trade name] can be used during breast-feeding.

Fertility

There is no information on the effects of [MA211 trade name] on fertility in humans.

Driving and using machines

[MA211 trade name] may cause dizziness and tiredness. If you feel dizzy or tired while taking [MA211 trade name], do not drive and do not use any tools or machines.

3. How to take [MA211 trade name]

Your health care provider will explain to you how many tablets of [MA211 trade name] to take. The dose depends on your weight. You must take the medicine for 3 days with no breaks in between.

The usual doses of the medicine for patients of different weights are described below:

Patient's weight	**Time**					
	Day 1		**Day 2**		**Day 3**	
	Immediately after diagnosis/ onset of symptoms	*8 hours after previous dose*	*12 hours after previous dose*	*12 hours after previous dose*	*12 hours after previous dose*	*12 hours after previous dose*
From 5 kg up to 15kg	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet
From 15kg up to 25kg	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets
From 25kg up to 35kg	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets
From 35kg	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets

Take the first dose immediately when your health care provider has diagnosed malaria.

Take the second dose 8 hours after the first dose.

Then take the remaining doses 12 hours apart.

Take [MA211 trade name] with food or a milky drink. 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, [MA211 trade name] should still be taken, but your body may take up less of the medicine.

If you vomit within 1 hour of taking the medication, you should repeat the dose.

You should always take [MA211 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.

If you take more [MA211 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 [MA211 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 six doses of this regimen**.

If you stop taking [MA211 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, [MA211 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.

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

However, some side effects could be serious and need immediate medical attention. Allergic (hypersensitivity) reactions may occur rarely, in up to 1 person in 1000.

- If you get a rash, swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, **tell your health care provider straight away**.

Of the other side effects that may occur with [MA211 trade name], the *most commonly* reported side effects (in more than 1 in every 10 patients treated) include

- fast heart beat (palpitations)
- headache
- dizziness
- cough
- nausea (feeling sick) or vomiting (being sick)
- abdominal (belly) pain
- decreased appetite
- joint pain
- muscle pain
- general weakness or tiredness
- sleep disorders.

Other *common* side effects (reported in more than 1 in every 100 patients treated) include

- changes in the electrical activity of the heart (QT-prolongation) seen in tests
- abnormal blood tests for liver function
- rash
- itching
- diarrhoea
- abnormal walking*
- needles and pins (paraesthesia) or numbness of the hands and feet*
- involuntary, rhythmic, muscular contractions (clonus)
- insomnia.

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

- clumsiness or difficulty in making movements smoothly (ataxia)*
- decreased skin sensitivity*
- sleepiness
- nettle rash (urticaria).

*These side effects have been reported in adults and adolescents above 12 years of age.

There have also been some reports of anaemia (low numbers of red blood cells) due to breakdown of the red blood cells, which has been reported up to a few weeks after treatment has been stopped (delayed haemolytic anaemia). It is not clear how often this may occur.

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 [MA211 trade name]

Do not store above 30°C, protect from light.
Keep this medicine out of the sight and reach of children.

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

Do not use this medicine if you notice 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 [MA211 trade name] contains

- The active ingredients are artemether and lumefantrine. Each tablet contains 20mg artemether and 120 mg lumefantrine.
- The other ingredient(s) of [MA211 trade name] are microcrystalline cellulose, croscarmellose sodium, polysorbate 80, maize starch, purified talc 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 [MA211 trade name] looks like and contents of the pack

[MA211 trade name] are yellow, round, uncoated tablets. They are flat on the top and bottom with a beveled edge. The tablets have a break line on one side and are plain on the other side.

[MA211 trade name] is packed as clear plastic (PVC/Aclar) on aluminium foil blister cards, each containing 6, 12, 18 or 24 tablets. Available in cartons of 1×6, 1×12, 1×18 or 1×24; 30×6, 30×12, 30×18 or 30×24 tablets

Supplier and Manufacturer

Supplier

Quality Chemical Industries Limited
Plot 1-7, 1st Ring Road,
Luzira Industrial Park,
P.O. Box 34871,
Kampala-Uganda.
Telephone: +256-312-341100
Email: contactus@qcil.com

Manufacturer

Quality Chemical Industries Limited
Plot 1-7, 1st Ring Road,
Luzira Industrial Park,
P.O. Box 34871,
Kampala-Uganda.
Telephone: +256-312-341100
Email: contactus@qcil.com

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

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