

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

[MA064 trade name][†]
Artemether/lumefantrine

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 [MA064 trade name] is and what it is used for
2. What you need to know before you take [MA064 trade name]
3. How to take [MA064 trade name]
4. Possible side effects
5. How to store [MA064 trade name]
6. Contents of the pack and other information

1. What [MA064 trade name] is and what it is used for

This medicine is an antimalarial. It is used to treat a certain type of malaria infection in adults and children.

[MA064 trade name] contains two antimalarial drugs, artemether and lumefantrine in fixed dose, which work together to kill the malaria parasite (a tiny organism that is found inside the red blood cells).

Your health care provider has found that you have malaria and so has prescribed [MA064 trade name]. It is indicated only for the treatment of so called uncomplicated malarial attacks due to *Plasmodium falciparum* (a particular type of malaria parasite).

For complete cure it is important that you complete the prescribed dose as advised by your health care provider.

2. What you need to know before you take [MA064 trade name]

Do not take [MA064 trade name]:

- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of the [MA064 trade name] listed at the end of this leaflet.
- If you have a severe type of malaria infection that affects the brain, or any other severe complications of malaria (for example affecting the lungs or kidneys).
- If you have a heart condition, such as changes in the rhythm or rate of the heartbeat, e.g. called “prolongation of the QT interval”, slow heartbeat, or severe cardiac 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 “Taking other medicines”).
- 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 [MA064 trade name].**

- If you think you may be allergic, ask your health care provider for advice.

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

Warnings and precautions

Talk to your health care provider **before taking [MA064 trade name]**:

- If you have severe liver or kidney problems.

Take special care with [MA064 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 [MA064 trade name].
- If you are infected with both, *Plasmodium falciparum* and *Plasmodium vivax*, your health care provider will give you another medicine for you to take after completing [MA064 trade name] treatment.

Other medicines and [MA064 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 [MA064 trade name], or [MA064 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 (medication to alleviate mood disorders)
- Antibiotics
- Antihistamines (for treatment of, e.g., allergies)
- Cisapride (a medicine for improving gastric motility)
- 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)

[MA064 trade name] with food and drink

[MA064 trade name] should be taken with food or a milky drink.

Pregnancy, breast-feeding and fertility

Pregnancy

During the first three months of pregnancy use [MA064 trade name] only with medical advice.

Later in pregnancy [MA064 trade name] can be used.

Breast-feeding

The actives of [MA064 trade name] appear in low amounts in human milk, but at therapeutic doses no effects on the breast-fed baby are anticipated. [MA064 trade name] can be used during breast-feeding.

Fertility

There is no information on the effects of [MA064 trade name] on fertility in humans.

Driving and using machines

[MA064 trade name] may cause dizziness and fatigue. If you feel dizzy or fatigued while taking [MA064 trade name], do not drive and do not use any tools or machines.

3. How to take [MA064 trade name]

[MA064 trade name] should always be taken exactly as described by the health care provider.

You should check with your health care provider if you are not sure.

Weight range	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
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 (or ≥ 12 years of age)	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.

Take the following doses 12 hours apart.

Take [MA064 trade name] with food or a milky drink. If you are unable to tolerate food, [MA064 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.

If you take more [MA064 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.

If you forget to take [MA064 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 [MA064 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, [MA064 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.

Some side effects could be serious and need immediate medical attention.

Rare (may affect up to 1 in 1,000 people):

If you get a rash, swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, tell your doctor straight away. These are signs of an allergic reaction.

Other side effects are:

The *most commonly* reported side effects (greater than 1 in every 10 patients treated) include fast heart beat (palpitations), headache, dizziness, nausea, vomiting, abdominal pain, decreased appetite, joint pain, muscle pain, general weakness, tiredness, sleep disorders.

Commonly (greater than 1 in every 100 patients treated) reported side effects include alterations to the electrocardiogram (QT-prolongation), 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 lack of voluntary coordination of muscle movements (ataxia)*, decreased skin sensitivity*, somnolence, itching rash (such as urticaria).

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

Not known (frequency cannot be estimated from the available data): anaemia due to breakdown of red blood cells, which has been reported up to a few weeks after treatment has been stopped (delayed haemolytic anaemia).

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 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 [MA064 trade name]

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

Do not store above 30°C. Protect from Light. Store in the original package.

Do not use this medicine after the expiry date stated on the carton or blister pack, 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 [MA064 trade name] contains

- The active ingredients are artemether and lumefantrine.
- The other ingredients of [MA064 trade name] are: croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, polysorbate 80 and purified talc.

What [MA064 trade name] looks like and contents of the pack

Yellow, circular, flat, bevelled, uncoated tablets with a central break-line on one side and plain on other side.

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

[MA064 trade name] is available in:

- Aluminium /PVC-Aclar blisters. Pack size: 1x6, 1x12, 1x18, 1x24, 30x6, 30x12, 30x18 and 30x24 tablets.
- Aluminium-aluminium blister foils. Pack sizes: 1x6 (6), 2x6 (12), 3x6 (18) or 4x6 (24) tablets.

Supplier and Manufacturer

Supplier

Cipla Ltd.,
Cipla House,
Peninsula Business Park,
Ganpatrao Kadam Marg, Lower Parel,
Mumbai, Maharashtra - 400 013,
India

Phone: +91-22-24826000

Fax: + 91-22-24826120

Email: globalra@cipla.com

Manufacturers

Cipla Patalganga

Unit II, Plot No. A-33 & A- 42, MIDC Patalganga
410220

Dist: Raigad, Maharashtra State
India

M/s Cipla Ltd,

Unit IV

Plot Nos L-139 to L-146

Verna Industrial Estate, Verna, Salcette, Goa
403722, India

Cipla Ltd Indore,

Unit IV Plot no 9 and 10 SEZ Phase-II,
Pithampur

Dist Dhar (M.P.) 454775

India

Quality Chemical Industries Ltd,

Plot No. 1-7, Ring Road,

Luzira Industrial Park,

P.O. Box 34871, Kampala, Uganda

For any information about this medicine, contact the supplier.

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