

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.¹

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

Information for the patient

[MA167 trade name]²

Artemether/lumefantrine

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 [MA167 trade name] is and what it is used for
2. What you need to know before you take [MA167 trade name]
3. How to take [MA167 trade name]
4. Possible side effects
5. How to store [MA167 trade name]
6. Contents of the pack and other information

1. What [MA167 trade name] is and what it is used for

[MA167 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.

¹ https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

² Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Malaria is caused by a parasite that is spread by mosquitoes. [MA167 trade name] is used for treating malaria caused by the parasite called *Plasmodium falciparum* when the infection is not severe enough to affect the brain or other key organs.

2. What you need to know before you take [MA167 trade name]

Do not take [MA167 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) – you will need treatment with different malaria medicines.
- if you have a heart condition, such as irregular heartbeats (arrhythmias), abnormal electrical activity of the heart called prolonged QT interval, slow heartbeat, or severe heart disease.
- if any member of your family (e.g. parent, grandparent, brother and sister) has died suddenly from a heart rhythm problem or is known to have been born with heart rate problems.
- if you are taking certain medicines (see “Other medicines and [MA167 trade name]”). - 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 [MA167 trade name].

Warnings and precautions

This medicine contains lactose and it may contain traces of cow’s milk protein. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency or if you are allergic to cow’s milk you must talk to your health care provider before taking this medicine.

Talk to your health care provider **before taking** [MA167 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 [MA167 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 [MA167 trade name].
- [MA167 trade name] is used to treat malaria caused by *Plasmodium falciparum*. If you are also infected with another type of malaria parasite, *Plasmodium vivax*, your health care provider will give you another medicine to take after completing [MA167 trade name] treatment.

Other medicines and [MA167 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. They may affect how well [MA167 trade name] works, or [MA167 trade name] may affect how well the other medicines work. 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 certain types of mental illness)
- Antidepressants (medicines for depression and low mood)

- Antibiotics
- Antihistamines (for treatment of allergies such as hay fever)
- Medicines to treat HIV infection
- Medicines to treat hepatitis B or hepatitis C infection
- Medicines to treat fungal infection
- Hormonal methods of birth control (for example birth control pills or contraceptive patch)

[MA167 trade name] with food and drink

Take [MA167 trade name] with food or a milky drink.

Pregnancy, breast-feeding and fertility

Pregnancy

[MA167 trade name] can be used during pregnancy.

Breast-feeding

The amounts of the active substances of [MA167 trade name] that pass into breast milk are low and [MA167 trade name] can be used during breast-feeding.

Fertility

There is no information on the effects of [MA167 trade name] on fertility in humans.

Driving and using machines

[MA167 trade name] may cause dizziness and tiredness. If you feel dizzy or tired while taking [MA167 trade name], do not drive and do not use any tools or machines that need you to be alert.

3. How to take [MA167 trade name]

Your health care provider will tell you how many tablets of [MA167 trade name] to take. The dose depends on your weight. You must take the medicine for 3 days.

The usual doses of [MA088 trade name] are shown below.

Patient's weight	Day 1		Day 2		Day 3	
	<i>As soon as possible</i>	<i>8 hours after previous dose</i>	<i>12 hours after previous dose</i>	<i>12 hours after previous dose</i>	<i>12 hours after previous dose</i>	<i>12 hours after previous dose</i>
5 kg to less than 15 kg	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet
15 kg to less than 25 kg	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets
25 kg to less than 35 kg	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets
35 kg or more	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets

Take the first dose as soon as you receive your supply of [MA088 trade name].

Take the second dose 8 hours after the first dose.

Then take the remaining doses 12 hours apart.

Take [MA167 trade name] with food or a milky drink. If you can't swallow the tablets whole, you may crush the tablet and add the powder to a small amount of soft food or liquid, all of which you should take immediately.

If you are not able to eat, you should still take [MA088 trade name], but less medicine will get into your body to work against the malaria parasite.

If you vomit within 1 hour of taking the medication, you should take another dose as soon as you can.

You should always take [MA167 trade name] exactly as your health care provider has told you and complete the 3-day course of tablets. Check with your health care provider if you are not sure.

If you take more [MA167 trade name] than you should

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

If you forget to take [MA167 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 can. Then take the next dose after about 12 hours. Do not take a double dose to make up for a forgotten tablet. Make sure you take all six doses of this medicine.

If you stop taking [MA167 trade name]

Take this medicine until you finish the course, 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, [MA167 trade name] can cause side effects, although not everybody gets them. It is important that you tell 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 [MA088 trade name], the *most commonly* reported side effects (in more than 1 in every 10 patients treated) include

- fast heart beat
- 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, muscle twitching (clonus) – difficulty sleeping (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 [MA167 trade name]

[MA167 trade name] should not be stored above 30°C. Protect from light. Store in the original packaging.

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 signs of deterioration and the tablets look 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 [MA167 trade name] contains

The active ingredients are artemether 20 mg and lumefantrine 120 mg.

The other ingredient(s) of [MA167 trade name] are anhydrous lactose, croscarmellose sodium, colloidal anhydrous silica, hypromellose, polysorbate 80, 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 [MA167 trade name] looks like and contents of the pack

'[MA167 trade name] is a yellow, circular, uncoated, matt-finished tablet. The tablet is flat-faced and beveledged. The tablets have a break line on one side and are plain on other side.'

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

The tablets are packed in either clear PVDC/PVC-Alu blister cards or clear PVC/PVDC-Alu blister cards.

The presentations are as follows:

- Carton containing 1 blister of 6 tablets
- Carton containing 2 blisters of 6 tablets
- Carton containing 3 blisters of 6 tablets
- Carton containing 4 blisters of 6 tablets

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- Outer printed box containing 30 monocartons with 1 blister of 6 tablets
- Outer printed box containing 30 monocartons with 1 blister of 12 tablets
- Outer printed box containing 30 monocartons with 1 blister of 18 tablets
- Outer printed box containing 30 monocartons with 1 blister of 24 tablets
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- Outer printed box containing 30 blisters of 6 tablets
- Outer printed box containing 30 blisters of 12 tablets
- Outer printed box containing 30 blisters of 18 tablets
- Outer printed box containing 30 blisters of 24 tablets Not all pack sizes may be marketed.

Supplier and Manufacturer

Supplier

Laboratórios Basi - Indústria Farmacêutica, S.A.
Parque Industrial Manuel Lourenço Ferreira, lote
15
3450-232 Mortágua
Portugal
Tel: +351 231 920 250
Email: basi@basi.pt

Manufacturer

Ipca Laboratories Limited
Plot no. 255/1, Village Athal
Silvassa 396 230
Dadra, Nagar Haveli, Daman, and Diu
India

Laboratórios Basi - Indústria Farmacêutica, S.A.
Parque Industrial Manuel Lourenço Ferreira,
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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/pqweb/medicines>

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