

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

[MA124 trade name][†]
Artesunate

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 [MA124 trade name] is and what it is used for
2. What you need to know before you take [MA124 trade name]
3. How to take [MA124 trade name]
4. Possible side effects
5. How to store [MA124 trade name]
6. Contents of the pack and other information

1. What [MA124 trade name] is and what it is used for

The rectal capsule contains a medicine called artesunate. This belongs to a group of medicines called antimalarials.

[MA124 trade name] is to be used as pre-referral treatment for children less than 6 years of age, with suspected severe malaria. It is to be used when the child cannot get full treatment right away or obtain single dose artesunate injection. This medicine is to be used as emergency treatment until full treatment for the malaria can be given in the nearest hospital or health care facility.

This medicine is for use in children less than 6 years. However, information from its use in adults is also included to give a fuller picture of the medicine's effects.

2. What you need to know before you take [MA124 trade name]

Do not give [MA124 trade name]:

If the child is allergic to artesunate or related artemisinin derivatives or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your child's health care provider before giving [MA124 trade name]:

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

A single dose of [MA124 trade name] will not cure malaria, and it is dangerous for the child not to be followed up with a complete curative course of antimalarial treatment once a health facility has been reached.

[MA124 trade name] is NOT recommended for prevention of malaria

[MA124 trade name] is for severe malaria only, NOT recommended for uncomplicated malaria.

Other medicines and [MA124 trade name]

Tell your child's health care provider if the child is taking, or has recently taken any other medicines.

3. How to take [MA124 trade name]

Always give this medicine exactly as instructed. Check with your child's health care provider if you are not sure.

[MA124 trade name] is given rectally, and must not be swallowed.

This medicine should be inserted into the rectum beyond the anal verge, blunt end first.

When the rectal capsule is administered to young children, the caregiver should hold the buttocks of the child for 10 minutes after insertion to avoid ejection.

If the rectal capsule is expelled from the rectum within 30 minutes of insertion, another rectal capsule should be inserted immediately. Rectal capsule dissolve rapidly upon insertion. If a child has diarrhoea, the health care provider should be asked for advice, as the absorption of the drug in the case of diarrhoea is not known.

[MA124 trade name] will be given to a child as a single dose before referral to the nearest health clinic or hospital.

The table below indicates the number of rectal capsules determined by body weight.

<i>Patient weight</i>	<i>Number of (100 mg) rectal capsules</i>
Up to 10 kg	1 rectal capsule
Up to 20 kg	2 rectal capsules

When referral is not possible

If you cannot get the child to a hospital where full treatment is possible, give another dose 12 hours after the first one. As soon as your child can swallow medicine, stop giving [MA124 trade name] and start giving a different medicine called Artemisinin-based Combination Therapy (ACT). This will help finish treating the malaria.

Severe febrile illness

For community health workers and in places with limited diagnostic capacity for severe malaria, the guidance below should be followed for pre-referral treatment of a rapid onset of fever and symptoms, in children less than 6 years of age.

▪ if fever AND	Give rectal artesunate capsule (100 mg)
<ul style="list-style-type: none">▪ Convulsions or▪ Unusually sleepy or unconscious or▪ Not able to drink or feed anything or▪ Vomits everything	<ul style="list-style-type: none">▪ Age 2 months up to 3 years - 1 rectal capsule▪ Age 3 years to less than 6 years – 2 rectal capsules

If you have any further questions on the use of this medicine, ask your child's health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. It is sometimes not possible to differentiate between symptoms caused by the disease and side effects of the medicine.

Tell your child's health care provider if you notice any of the following side effects

- Headache
- Convulsions
- Vomiting
- Change in behaviour
- Walking problems (abnormal gait)
- Weakness
- Inability to sit supported
- Ringing in ears (tinnitus)
- Abnormal vision
- Speech problems

Tell your child's health care provider if you notice any other side effects not mentioned above.

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 [MA124 trade name]

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

Do not freeze or refrigerate. Do not store above 25°C.

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 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 [MA124 trade name] contains

- The active ingredient is artesunate. Each rectal capsule contains 100 mg of artesunate
- The other ingredients of [MA124 trade name] are:
 - Capsule shell: gelatin, glycerol and titanium dioxide
 - Fill blend: hard fat and medium chain triglyceride

What [MA124 trade name] looks like and contents of the pack

White to off-white elongated, soft gelatin capsules containing white to off-white paste.

Each carton contains one aluminium blister containing 2 rectal capsules.

Supplier and Manufacturer

Supplier

Cipla Limited
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel, Mumbai- 400 013 India
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Fax: +91-22-24826120
globalra@cipla.com

Manufacturer

Cipla Limited
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MIDC Industrial area
Kurkumbh
Dist: Pune 413 802
India
Phone: +91-2117-230108
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For any information about this medicine, please contact the supplier.

This leaflet was last revised in May 2025

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>