

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

[MA124 trade name][†]
Artesunate

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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as your child's.
- 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 give [MA124 trade name] to your child
3. How to give [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 suppository 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 under 6 years of age, with suspected severe malaria. It is to be used when the child cannot take medicines by mouth, and would normally be referred for injection, but cannot immediately or safely obtain injectable treatment. 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 intended for use in children under 6 years of age. Safety information on use in adults is also provided.

2. What you need to know before you give [MA124 trade name] to your child

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]:

A single dose of artesunate 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

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

[MA124 trade name] is NOT recommended for uncomplicated malaria, when the child can take oral medicines.

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 give [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 suppositories are administered to young children, the caregiver should hold the buttocks of the child for 10 minutes after insertion to avoid ejection.

If the suppository is expelled from the rectum within 30 minutes of insertion, another suppository should be inserted immediately. Suppositories 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.

This medicine is recommended for antimalarial treatment as a single dose of 10 mg/kg bodyweight.

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

Body Weight	Number of 100 mg suppositories
Up to 10 kg	1 suppository of 100 mg artesunate
Up to 20 kg	2 suppositories of 100 mg artesunate

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 under 6 years of age.

if fever AND	Give rectal artesunate suppository (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 suppository▪ Age 3 years up to 6 years – 2 suppositories

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 your child gets 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 provide more information on the safety of 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. Avoid excursions above 30°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 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 [MA124 trade name] contains

- The active ingredient is artesunate. Each suppository 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 coloured, elongated, soft gelatin capsules containing white to off white paste.

Carton having one Alu - Alu blister containing 2 suppositories.

Supplier and Manufacturer

Supplier

Cipla Limited
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel, Mumbai- 400 013
India
Tel: +91-22-24826000
Fax: +91-22-24826120
Email: globalra@cipla.com

Manufacturer

Cipla Limited
Plot no. D-7 (Unit 1)
MIDC Industrial area
Kurkumbh
Dist: Pune 413 802
India
Phone: ++91-2117-230108
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Cipla Limited

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MIDC Industrial Area,
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Dist: Pune – 413 802
India.

For any information about this medicine, contact the local representative of the supplier:

This leaflet was last revised in March 2021

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