

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

[MA123 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 [MA123 trade name] is and what it is used for
2. What you need to know before you take [MA123 trade name]
3. How to take [MA123 trade name]
4. Possible side effects
5. How to store [MA123 trade name]
6. Contents of the pack and other information

1. What [MA123 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.

[MA123 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 [MA123 trade name]

Do not give [MA123 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 [MA123 trade name]:

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

A single dose of [MA123 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.

[MA123 trade name] is NOT recommended for prevention of malaria

[MA123 trade name] is for severe malaria only, NOT recommended for uncomplicated malaria.

Other medicines and [MA123 trade name]

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

Driving and using machines

[MA123 trade name] is not likely to affect your ability to drive or operate machinery.

3. How to take [MA123 trade name]

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

[MA123 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.

[MA123 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 can not get the child to a hospital where full treatment is possible, give another dose of 12 hours after the first one. As soon as your child can swallow medicine, stop giving [MA123 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)
▪ Convulsions or	▪ Age 2 months up to 3 years - 1 rectal capsule

▪ Unusually sleepy or unconscious or ▪ Not able to drink or feed anything or ▪ Vomits everything	▪ Age 3 years to less than 6 years – 2 rectal capsules
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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 [MA123 trade name]

Do not freeze or refrigerate. Do not store above 25°C. Avoid excursions over 30°C.

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 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 [MA123 trade name] contains

- The active ingredient is artesunate
- The other ingredients of [MA123 trade name] are:
 - *Capsule shell*: gelatin, glycerol and titanium dioxide
 - *Fill blend*: hard fat and medium chain triglyceride

What [MA123 trade name] looks like and contents of the pack

[MA123 trade name] are teardrop-shaped, opaque off-white soft gelatin rectal capsules. They contain a white to off white oily mass

[MA123 trade name] are packed in aluminium foil on aluminium foil blister cards, each containing 2 soft gelatin rectal capsules. Available in a box of 1x2 soft gelatin rectal capsules.

Supplier and Manufacturer

Supplier

Strides Pharma Global Pte. Limited
1 Gateway Drive
#06-06
Westgate Tower
Singapore 608531
Tel: 65-6421 4680

Manufacturer

Strides Pharma Science Limited
KRS Gardens
Soft Gel Capsules Block
36/7, Suragajakkanahalli
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For any information about this medicine, contact the supplier:

This leaflet was last revised in October 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>

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