

**WHO-PQ RECOMMENDED
PATIENT INFORMATION LEAFLET**

ARTECAP¹

Artesunate 100 mg Suppositories

Read all of this leaflet carefully before giving this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions about this medicine, ask your health care provider.
- This medicine has been prescribed for children aged 2 months to 6 years who are unable to take oral medicine, and are unable to obtain injectable malaria medicine. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same.
- If the patient gets any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ARTECAP is and what it is used for
2. What you need to know before you give ARTECAP
3. How to give ARTECAP
4. Possible side effects
5. How to store ARTECAP
6. Contents of the pack and other information

1. What ARTECAP is and what it is used for

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

ARTECAP is to be used as pre-referral treatment for patients aged between 2 months and 6 years, with suspected severe malaria. It is to be used when the patient 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 cure for malaria can be given in the nearest hospital or health care facility.

This medicine is intended for use in children aged between 2 months and 6 years. Safety information on use in adults is also provided.

2. What you need to know before you give ARTECAP

Do not give ARTECAP:

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

¹Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Warnings and precautions

Talk to your child's health care provider before giving ARTECAP:

A single dose of artesunate will not cure malaria, and it is dangerous for the patient not to follow up with a complete curative course of antimalarial treatment once a health facility has been reached.

ARTECAP is NOT recommended for prevention of malaria

ARTECAP is NOT recommended for uncomplicated malaria, when the patient can take oral medicines.

Other medicines and ARTECAP

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

3. How to give ARTECAP

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

ARTECAP 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 10 mg/kg bodyweight single dose.

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

| Body Weight (kg) | Number of 100 mg suppositories |
|------------------|--------------------------------|
| ≤ 10 kg | 1 |
| ≤ 20 kg | 2 |

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.

| | |
|--|---|
| <ul style="list-style-type: none">▪ if fever AND<ul style="list-style-type: none">▪ Convulsions or▪ Unusually sleepy or unconscious or▪ Not able to drink or feed anything or▪ Vomits everything | Give rectal artesunate suppository (100 mg) <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.

5. How to store ARTECAP

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.
- Store at 25°C (77°F); excursions permitted between 15° to 30°C (59° to 86°F). Avoid excursions over 30°C. Do not freeze.

Do not throw away any medicines via 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 ARTECAP contains

- The active substance is artesunate. Each suppository contains 100 mg of artesunate.
- The other ingredients are:
 - Capsule shell: gelatin, glycerol and titanium dioxide
 - Fill blend: hard fat and medium chain triglyceride

What ARTECAP look like and contents of the pack

Ivory colored, elongated shaped, soft gelatin capsules containing white to off white coloured oily mass.

Carton with one Alu-Alu blister card containing 2 soft rectal capsules.

Supplier and Manufacturer

Supplier

Strides Pharma Global Pte Limited
3, Tuas South Avenue 4
Singapore – 637610
Tel. No: + (65) 6708 8505
Fax No: + (65) 6708 8506

Manufacturer

Strides Pharma Science Limited
KRS Gardens
Soft Gel Capsules Block
36/7, Suragajakkanahalli
Indlavadi cross
Anekal Taluk
Bangalore – 562 106
India

For any information about this medicinal product, please contact the supplier

This leaflet was last approved in November 2018.

Section 6 updated in May 2021.

Detailed information on this medicine is available on the World Health Organization (WHO) website:

<https://extranet.who.int/prequal>