

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Artesunate 50 mg tablets* Artesunate

-Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care worker or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist.

In this leaflet:

1. What Artesunate 50 mg tablets is and what it is used for
2. Before you take Artesunate 50 mg tablets
3. How to take Artesunate 50 mg tablets
4. Possible side effects
5. How to store Artesunate 50 mg tablets
6. Further information

1. WHAT ARTESUNATE IS AND WHAT IT IS USED FOR

Artesunate 50 mg tablets is used for the treatment of uncomplicated cases of malaria. Artesunate 50 mg tablets is indicated only for attacks due to *Plasmodium falciparum* (a particular type of malaria parasite), against which the medicine is active.

It reduces the number of malaria parasites in your body.

Your doctor has found that you have malaria and so has prescribed the tablets to treat your malaria infection. For complete cure it is important that you complete the prescribed dose as advised by your doctor, health care worker or pharmacist.

2. BEFORE YOU TAKE ARTESUNATE

Do not take Artesunate 50 mg tablets

- If you are hypersensitive (allergic) to artesunate or to any of the other ingredients of Artesunate 50 mg tablets (see section 6, What Artesunate 50 mg tablets contains),

Take special care with Artesunate 50 mg tablets

If you have experienced rash or urticarial reaction to artesunate before, you should not be treated with Artesunate 50 mg tablets, if avoidable, since this has been associated with recurrence of symptoms and occasionally with the development of severe allergic reactions (see section 4.3).

* Trade names are not prequalified by WHO. This is under local DRA responsibility.
Throughout this WHOPAR the proprietary name is given as an example only.

Since the use of artesunate has not been evaluated for the following conditions, Artesunate 50 mg tablets is NOT recommended:

- for the treatment of complicated malaria.
- for treatment of malaria due to other types of parasites (*Plasmodium vivax*, *Plasmodium malariae* or *Plasmodium ovale*).
- for prevention of malaria.

Artesunate has not been studied specifically in patients with special hereditary disorders of the blood called thalassaemia, sickle cell anaemia and G6PD deficiency.

Taking other medicines

Tell your doctor, health care worker or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Co-administration of Artesunate 50 mg tablets in combination with amodiaquine (another antimalarial medicine), and efavirenz, (a medicine for the treatment of HIV-infection) should be avoided, since this combination may cause marked liver damage

Pregnancy and breast feeding

Tell your doctor if you are pregnant or if you suspect you are pregnant. Artesunate 50 mg tablets should only be used during pregnancy if your doctor or health care worker has told you to do so. Breast feeding may be continued during therapy with Artesunate 50 mg tablets.

Driving and using machines

Artesunate 50 mg tablets can make you feel dizzy. If this occurs, you should not drive or use machines.

3. HOW TO TAKE ARTESUNATE 50 MG TABLETS

Always take artesunate tablets exactly as your doctor or health care provider has told you. Artesunate 50 mg tablets are usually taken in combination with another medicine to treat malaria.

Artemisinin-based combination therapy (ACT)

In combination therapy in adults and children, artesunate should be given at 4 mg/kg body weight once daily for three days (range 2-10 mg/kg; 200 mg per day in adults).

Artesunate dosing scheme in combination therapy (treatment duration 3 days)	
Age	No of tablets per day (dose)
1-6 years	1 tablet once daily (50 mg/day)
7-13 years	2 tablets once daily (100 mg/day)
Older than 13 years	4 tablets once daily (200 mg/day)

Single drug therapy (not usually recommended)

In case of allergy, intolerance or contraindication to combination agents, artesunate can be used as single therapy:

- in adults a total dose of 600-800 mg should be given during five to seven days of treatment, and
- in children a total dose of 12 mg/kg body weight should be given during five to seven days of treatment (see table below).

Example for artesunate dosing scheme in single drug therapy (treatment duration 5-7 days)		
Age	No of tablets per day (dose)	
	Day 1	Subsequent days
7-13 years	1 tablet twice daily (50 mg x 2)	1 tablet daily (50 mg x 1)
Older than 13 years	2 tablets twice daily (100 mg x 2)	1 tablet b.i.d (50 mg x 2)

No dose changes are needed for patients with kidney or liver problems.

Artesunate 50 mg Tablets should not be taken with a high-fat meal.

Swallow the tablet with water or another drink.

If you use more Artesunate 50 mg tablets than you should

If you have taken too many tablets or if someone accidentally swallows some, there is no immediate danger. However, you should contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Artesunate 50 mg tablets

When Artesunate 50 mg tablets is normally to be taken once daily (in combination therapy):

If you accidentally miss a dose take the missed dose as soon as possible. Make sure you take the next dose least 8 hours but not more than 24 hours after that dose. If your next regular dose is scheduled more than 8 hours after the dose made up for, then simply take your normal dose when it is due. Do not take a double dose to make up for forgotten individual doses.

When Artesunate 50 mg tablets is normally to be taken twice daily: If you accidentally miss a dose, take the missed dose as soon as possible. Take the next regular dose as scheduled. If you notice only when your next dose is due, you may take a double dose to make up for the forgotten individual dose.

If you stop taking Artesunate 50 mg tablets

Make sure that the medicine is administered for as long as your doctor has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured. This may result in relapse of your malaria symptoms, and possibly increased problems in treating malaria should you get it again.

You should not stop treatment unless your doctor or health care provider tells you to.

If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Artesunate 50 mg tablets can cause side effects, although not everybody gets them.

The following side effects are *uncommon* (between 1 in 1,000 and 1 in 100 patients treated): Slow heart rate, mild gastrointestinal disturbances, abnormal liver function tests (high liver enzyme levels in blood), low counts of pre-stages of red blood cells (reticulocytopenia), and low white blood cell counts.

There are *rare* reports (between 1 in 10 000 and 1 in 1000 patients treated) of severe allergic reactions.

Frequency *not known* (cannot be estimated from the available data): irregular heart rhythm, dizziness, ringing in ears and rash, sometimes with hives.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist.

5. HOW TO STORE ARTESUNATE 50 MG TABLETS

Keep out of the reach and sight of children.

Do not store above 30°C, Store in the original packaging.

Do not use Artesunate 50 mg tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use Artesunate 50 mg tablets if you notice any visible sign of deterioration.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Artesunate 50 mg tablets contains

The active ingredient is artesunate.

The other ingredients are

Microcrystalline Cellulose,
Corn Starch,
Hypromellose,
Sucrose,
Sodium Starch Glycolate (CMS-Na),
Magnesium Stearate

What Artesunate 50 mg tablets look like and contents of the pack

White round tablets, scored and imprinted on both sides of the tablet; imprint AS and imprint 50 mg on opposite sides of the score.

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

Artesunate 50 mg tablets are packaged with PVC/Aluminium blister cards containing 12 tablets. The blisters are further packaged in cardboard boxes.

Supplier and Manufacturer

Guilin Pharmaceutical Co. Ltd
No 17, Shanghai Road,
Guilin, Guanxi
People's Republic of China
Tel.: 86-773-3833116
Fax: 86-773-3832783
e-mail: glpharma@public.glptt.gx.cn

Guilin Pharmaceutical Co. Ltd
No.43 Qilidian Road,
Qixing, Guilin,
People's Republic of China

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

This leaflet was last approved in 02/2009. Section 6 updated in March 2013.

Detailed information on this medicine is available on the WHO Prequalification web site:
<http://www.who.int/prequal/>