PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Artesun®*

Artesunate 60 mg for injection and sodium bicarbonate injection 50 mg/ml (1ml) and sodium chloride injection 9 mg/ml (5ml) for preparation of solution for intravenous or intramuscular injection

Read all of this leaflet carefully.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please consult your doctor, health care provider or your pharmacist.
- This medicine is exclusively used in hospitals and clinics, and should only be administered by qualified medical personnel.

In this leaflet:

1. What is **Artesun®** and what it is used for.
2. What you need to know before use of **Artesun®**.
3. How **Artesun®** is used.
4. Possible side effects of **Artesun®.**
5. How **Artesun®** is stored.
6. Further information

1. WHAT ARTESUN® IS AND WHAT IT IS USED FOR

Artesun® is for preparation of a solution for intravenous or intramuscular injection.

Artesun® is used for the treatment of severe *falciparum* malaria caused by the parasite *Plasmodium falciparum.*

2. BEFORE USE OF ARTESUN®

Artesun® should not be used:
If the person is hypersensitive (allergic) to any component of this product.

Take special care with Artesun®
After intravenous or intramuscular treatment of the critical phase of the *falciparum* malaria infection, the person will need to take oral medication to complete the treatment and avoid relapse.

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* Trade 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.

Taking other medicines
Please inform the doctor, health care provider or pharmacist if the person is taking or has recently taken any other medicines, including medicines bought without prescription

Pregnancy and breast-feeding
This medicine may need to be used when the person is pregnant. A small amount of the medicine enters human breast milk, but it will not protect the child from malaria. The doctor or health care provider will advise the person on breast-feeding.

3. HOW ARTESUN® IS USED

Artesunate may be injected intravenously (into a vein) or intramuscularly (into a muscle).

The duration of treatment is at least one day, and will be determined by the doctor or health care provider.

For each dose a new syringe and injection needle must be used.

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, **Artesun®** can cause side effects, but not everybody gets them. Some of these may be difficult to detect, and may be similar to effects of the disease itself.

Common side effects (reported in 1 to 10 out of 100 patients):
Dizziness, feeling sick, vomiting, light-headedness, headache, sleeplessness, hearing problems, 'flu-like effects (including fever, tiredness, bone and muscle pain), cough, altered taste, abdominal pain, diarrhoea, rash, and pain at injection site.

Uncommon side effects (reported between 1 in 1000 and 1 in 100 patients treated):
Anaemia (low red blood cell count), neutropenia (low white blood cell count), reduction in platelets (which are important for blood clotting) and allergic reactions.

Rare side effects (reported in less than 1 in 1000 patients):
Inflammation of the liver (hepatitis, with yellowing of eyes and skin) and inflammation of the pancreas (pancreatitis).

Very rare side effects (reported in less than 1 in 10,000 patients):
Severe reduction in red blood cells, tingling sensation and nerve pain.

Frequency not known:
Anaemia has been reported after treatment but it is not known how frequently this effect occurs.

5. HOW ARTESUN® IS STORED
Artesun® should be kept out of the sight and reach of children.

Artesun® is stored in the original packing, below 30° C, until it is ready to be used to create a solution. The reconstituted and diluted solutions should be stored below 30°C and the total in-use period should not exceed one hour.

Protect against direct sunlight. Do not store in a refrigerator or freezer.

The product must be destroyed if crystals or cloudiness are visible in the solution.

Do not use **Artesun®** after the date indicated by "EXP -----" on the immediate and the outer labelling.

6. FURTHER INFORMATION

What Artesun® contains
The active substance is artesunate
The other ingredient sodium bicarbonate solution is used for dissolving the artesunate and the sodium chloride injection is used as diluent.

What Artesun® looks like and contents of the pack
Artesunate for injection is a sterile white crystalline powder, 60 mg.
Sodium bicarbonate injection is a sterile clear colourless liquid, 50 mg/ml, 1 ml.
Artesun® is supplied in a carton box.

Supplier and Manufacturer

Guilin Pharmaceutical Co., Ltd.;
No. 43 Qilidian Road
Guilin,
Guangxi, China
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Fax: +86 773 2670530
Email: glpharma@public.glptt.gx.cn

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

This leaflet was last revised in 06/2013.

Detailed information on this medicine is available on the World Health Organization (WHO) website: http://www.who.int/prequal/

This information is intended for medical or healthcare professionals only:

INFORMATION FOR HEALTHCARE PROFESSIONALS

Artesun®
Artesunate for injection

Please refer to the Summary of Product Characteristics for full prescribing information.
Posology and method of administration

Dose:
Adults and children: **Artesun®** is administered at a dose of 2.4 mg of artesunate / kg body weight, by intravenous (IV) or intramuscular (IM) injection, at 0, 12 and 24 hours, then once daily until oral treatment can be substituted.

Artesun® should be administered for a minimum of 24 hours (3 doses), regardless of the patient's ability to tolerate oral medication earlier. After at least 24 hours of **Artesun®**, and when able to tolerate oral medication, the patient should be switched to a complete treatment course of an oral combination antimalarial regimen. Relevant treatment guidelines should be consulted when selecting an appropriate regimen (e.g. those of the WHO: http://www.who.int/malaria/en/).

Preparation
Because of the instability of artesunate in aqueous solutions the reconstituted solution must be used within one hour of preparation. Therefore the required dose of artesunate should be calculated (dose in mg = patient's weight in kg x 2.4) and the number of vials of artesunate needed should be determined prior to reconstituting the artesunate powder.

Reconstitution of the artesunate solution
1. Using a syringe, withdraw 1 ml of the supplied sodium bicarbonate solvent from the ampoule
2. Inject the sodium bicarbonate into the vial containing the artesunate powder.
3. Shake the vial for several minutes to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
4. The reconstituted artesunate solution should always be used immediately, and discarded if not used within one hour.

Following reconstitution the solution must be diluted according to the method of injection, as described below.

Dilution for intravenous (IV) injection

1. Using a syringe, add 5 ml of sodium chloride 0.9% for injection to the vial containing the reconstituted artesunate solution. This will yield 6 ml of a solution containing artesunate 10 mg/ml.
2. Shake to mix well, ensuring that the resulting solution is still clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
   The volume required will be equal to: $\frac{\text{(desired dose in mg)}}{10}$ ml
3. Withdraw the required volume of artesunate solution from the vial with a syringe
4. Then inject slowly intravenously, the speed of IV consistent with slow bolus: 3-4 ml/min.

Artesun® should NOT be administered as an intravenous drip.

Dilution for intramuscular (IM) injection

1. Using a syringe, add 2 ml of sodium chloride 0.9% for injection to the vial containing the reconstituted artesunate solution. This will yield 3 ml of a solution containing artesunate 20 mg/ml.
2. Shake to mix well, ensuring that the resulting solution is still clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
   The volume required will be equal to: $\frac{\text{(desired dose in mg)}}{20}$ ml
3. Withdraw the required volume of artesunate solution from the vial with a syringe and then inject intramuscularly; the anterior thigh is usually the preferred site for injection. If the total volume of solution to be injected intramuscularly is large, it may be preferable to divide the volume and inject it at several sites, e.g. both thighs.

Do not use water for injection for reconstitution of the artesunate powder or for dilution of the resulting solution prior to injection.