PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
Artesun® 120mg*
Artesunate 120 mg for injection and sodium bicarbonate injection 50 mg/ml (0.5ml) and sodium chloride injection 9 mg/ml (2.5ml) 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 health care provider.
- This medicine is exclusively used in hospitals and clinics, and should only be administered by qualified medical personnel.

In this leaflet:

1. WHAT ARTESUN® 120mg IS AND WHAT IT IS USED FOR

Artesun® 120mg contains artesunate and is for preparation of a solution for intravenous or intramuscular injection.

Artesun® 120mg is used for the treatment of severe *falciparum* malaria caused by the parasite *Plasmodium falciparum.*

2. WHAT YOU NEED TO KNOW BEFORE USE OF ARTESUN® 120mg

Artesun® 120mg should not be used
If the patient is allergic to the active substance or any of the other ingredients of this product (see section 6).

Warnings and Precautions®
After intravenous or intramuscular treatment of the critical phase of the *falciparum* malaria infection, the patient will need to take oral medication to complete the treatment and avoid relapse.

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

Delayed haemolytic anaemia (a reduction of red blood cells) within the first month after treatment with Artesun has been reported, particularly in small children and travelers. The health care provider may therefore monitor the patient's blood count within 28days after malaria therapy. If you feel excessively tired, weak or short of breath up to 4 weeks after treatment, inform your health care provider.

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

Pregnancy and breast-feeding
Pregnancy
Severe malaria is especially hazardous during pregnancy, therefore full dose parenteral artesunate treatment should be administered at any stage of pregnancy without delay.

Breast-feeding
A small amount of the medicine enters human breast milk, but it will not protect the child from malaria. The health care provider will advise the patient on breast-feeding.

3. HOW ARTESUN® 120mg 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 health care provider.

For each dose a new syringe and injection needle must be used. Further information on the method of administration for the health care professionals is attached to this leaflet.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Artesun® 120mg** 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.

Very common side effects (≥ 1/10):
Post-treatment haemolytic anaemia (low red blood cells) in travelers and children, sometimes serious.
Mild and transient decrease in reticulocyte count (blood elements important for clotting).

Common side effects (1/100-1/10):
Dizziness, vomiting, light-headedness, headache, altered taste, abdominal pain or cramps, diarrhoea, rash, pain at injection site, insomnia, tinnitus (ringing in ears, with or without decrease in hearing), cough and / or nasal symptoms, nausea, hair loss, joint pain, bone and muscle disorders, fatigue, malaise, and fever.

Uncommon side effects (1/1000-1/100):
Low red and white blood cell counts, clotting factor decreases, rises in liver enzymes, allergic reactions, heart rhythm and rate problems.

Rare side effects (1/10,000-1/1000)
Inflammation of the liver or pancreas. Bile stones. Artery narrowing, high blood pressure affecting the eyes.

Very rare side effects (< 1/10,000):
Severe reduction in red blood cells, tingling sensation and nerve pain.

5. HOW TO STORE ARTESUN® 120mg

Artesun® 120mg should be kept out of the sight and reach of children.

Artesun® 120mg 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 30ºC 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® 120mg** after the date indicated by "EXP -----" on the immediate and the outer labelling.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Artesun® 120mg contains
Artesunate powder for injection (no other excipients)
Solvent: sodium bicarbonate and water for injection
Diluent: sodium chloride and water for injection

What Artesun® 120mg looks like and contents of the pack
Artesunate for injection is a sterile white crystalline powder, 120 mg.
Sodium bicarbonate injection is a sterile clear colourless liquid, 50 mg/ml, 2 ml.
Diluent: Sodium chloride injection is a sterile clear colourless liquid, 9 mg/ml, 10 ml.
Artesun® 120mg is supplied in a plastic tray in a carton box.

Supplier and Manufacturer
Guilin Pharmaceutical Co., Ltd.;
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For information about this medicinal product, please contact the supplier.

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Section 4 was updated in January 2020

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

This information is intended for healthcare professionals only:

INFORMATION FOR HEALTHCARE PROFESSIONALS

Artesun® 120mg
Artesunate for injection

Please refer to the Summary of Product Characteristics for full prescribing information.

Posology and method of administration

Dose:
Adults and children weighing at least 20 kg: **Artesun® 120mg** 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.

*Children weighing less than 20 kg***: Artesun® 120mg** is administered at a dose of 3 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® 120mg 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® 120mg**, 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/publications/atoz/9789241549127/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 or dose in mg = patient's weight in kg x 3 for children weighing less than 20 kg, respectively) 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 2 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 (10 mg/ml)

1. Using a syringe, add 10 ml of sodium chloride 0.9% for injection to the vial containing the reconstituted artesunate solution. This will yield 12 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 of the solution required (ml) will be:
   Volume (ml) = [dose (mg)] ÷ 10
3. Withdraw the required volume of artesunate solution from the vial with a syringe
4. Then inject slowly intravenously, over 1-2 minutes.

Artesun® 120mg should NOT be administered as an intravenous drip.

Dilution for intramuscular (IM) injection (20 mg/ml)

1. Using a syringe, add 4 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 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 of the solution required (ml) will be:
   Volume (ml) = [dose (mg)] ÷ 20
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.