WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

This patient information leaflet focuses on uses of the medicine covered by WHO'sPrequalification 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

[MA194 trade name] †

Artesunate+sodium bicarbonate+sodium chloride

The warnings and instructions in this leaflet are intended for the person taking the medicine. If you are a parent or carer responsible for giving the medicine to someone else such as a child, you will need to apply the instructions accordingly.

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 get 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 [MA194 trade name] is and what it is used for

[MA194 trade name] is a medicine used to treat severe malaria in adults and children. It contains the active substance artesunate and is made up into a solution that is injected into a vein or a muscle.

Malaria is caused by infection with a parasite called *Plasmodium,* spread by the bite of an infectedmosquito. [MA194 trade name] is used when the malaria is caused by a type of malaria parasite called*Plasmodium falciparum* and only when the infection is severe enough that it cannot be treated with medicines by mouth.

Your health care provider will follow the most recent official guidelines on the use of malaria medicinesto select the right medicine for your malaria treatment.

2. What you need to know before you are given [MA194 trade name]

[MA194 trade name] should **not be used** if you are allergic to the active substance or any of the other ingredients of this product (see section 6).

Warnings and precautions

After you have been treated with [MA194 trade name]to bring down the most severe symptoms of your malaria infection, you will need to take malaria medicines by mouth to complete the treatment.

Some people treated with this medicine have developed increased breakdown of red blood cells in the body after treatment has finished, leading to low red blood cell levels within the first month after therapy., This has been seen most often in small children and travelers. Your health care provider may carry out blood tests to check for this for the first few weeks after treatment.

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

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 breastfeeding

Pregnancy

Severe malaria is especially dangerous during pregnancy, so if you need treatment with [MA194 trade name]it will be given to you. Use during pregnancy is not expected to cause harm to you or the unborn baby.

Breastfeeding

A small amount of the medicine enters human breast milk, but if you are well enough to breastfeed this is not expected to cause any problems for your baby. However, there is not enough medicine to protect the child from malaria.

3. How [MA194 trade name] is given

Artesunate is given by injection into a vein or into a muscle (usually the muscle of your thigh). The dose is based on your weight. Your health care provider will work out the right dose to give.

Treatment is given for at least a day, until you are well enough to be treated by malaria medicines taken by mouth.

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

4. Possible side effects

Like all medicines, [MA194 trade name] 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 (may affect up to 1 in 10 people):

Dizziness, feeling sick, vomiting, light-headedness, headache, sleeplessness, hearing problems or ringing in the ears, slow heart rate (bradycardia), low blood pressure, fever, tiredness, joint and muscle pain, cough, irritated or runny nose, altered taste, abdominal pain, diarrhoea, rise in liver enzymes (may indicate liver damage), rash, hair loss and pain at injection site.

Uncommon side effects (may affect up to 1 in 100 people):

Anaemia (low red blood cell count, see also below), neutropenia (low numbers of white blood cells which are important to fight infections), increased levels of a substance called bilirubin seen in blood tests, yellowing of eyes or skin (jaundice), reduction in platelets (which are important for blood clotting),severe painful rashes with flu-like symptoms (Stevens-Johnson syndrome), itching, and allergic reactions.

Rare side effects (may affect up to 1 in 1,000 people):

Inflammation of the liver (hepatitis) and inflammation of the pancreas (pancreatitis).

Very rare side effects (may affect up to 1 in 10,000 people):

Severe reduction in red blood cells, tingling sensation and nerve pain.

Not known (frequency cannot be estimated from the available data):

Abnormal electrical activity of the heart.

Anaemia (low red blood cells) may occur within one month after treatment. It has been reported especially in young children and in travelers. If you feel excessively tired, weak or short of breath up to 4 weeks after treatment, inform your healthcare provider.

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 [MA194 trade name]

Keep this medicine out of the sight and reach of children.

Do not store above 25°C, in a dry place. Keep the vial and ampoules in the provided carton to protect the products from light. Do not refrigerate or freeze.

This medicine must not be used after the expiry date stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine must not be used if there is description of the visible signs of deterioration or 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 [MA194 trade name] contains

- The active ingredient is artesunate powder for injection. No other excipients.
- The solvent is consist of sodium bicarbonate, disodium edetate and water for injection that give a concentration of 50 mg/mL
- The diluent is consist of sodium chloride and water for injection that give a concentration of 9 mg/mL.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [MA194 trade name] looks like and contents of the pack

Artesunate powder for injection is a sterile white powder, 120 mg

It is filled in a 15mL clear glass vial (USP Type III.) The filled vial is closed with 20mm grey bromobutyl rubber plug and sealed with 20mm dark green flip off aluminium seal.

Sodium bicarbonate Injection (solvent) is a clear colourless liquid, 50 mg/mL

The solvent is filled in a 1 mL clear glass ampoule (USP Type I) with a green snap off ring.

Sodium chloride Injection (diluent) is a clear colourless liquid, 9 mg/mL

The diluent is filled in a 5 mL clear glass ampoule (USP TypeI)

Pack size: MA194 is supplied in a carton comprised of one vial of artesunate powder for injection, two ampoules of sodium bicarbonate injection, two ampoules of sodium chloride injection placed in a plastic tray along with a package insert.

Supplier and Manufacturer

Supplier

Macleods Pharmaceuticals Limited
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'For any information about this medicine, contact the supplier'.

This leaflet was last revised in July 2024

Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products

This information is intended for health care providers only:

Instructions for reconstitution
When reconstituted correctly, one vial of [MA194 trade name] will yield 12 mL of a solution for intravenous administration (10 mg/mL) or 6 mL of a solution for intramuscular administration (20 mg/mL).

For patients weighing over 50 kg, more than 1 vial of [MA194 trade name] will be needed for each dose. The required number of product packs should be determined as follows.

Patient weight	Number of vials of artesunate (120 mg) needed
up to 50 kg	1
51 to 100 kg	2

- Using a syringe, withdraw 1 mL of the supplied sodium bicarbonate solvent from the ampoule and inject into the vial containing the artesunate powder.
- 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.
- The reconstituted solution should then be diluted using the appropriate amount of supplied diluent (sodium chloride 0.9% for injection) according to the intended route of administration, as follows:

	For intravenous use	**For intramuscular use**
Volume of bicarbonate solvent	2 mL	2 mL
Volume of sodium chloride diluent	10 mL	4 mL
Total volume	12 mL	6 mL
Concentration of final artesunate solution	10 mg/mL	20 mg/mL

Once reconstituted, the artesunate solution must be used within one hour.