WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

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

[MA200 trade name] †
Artesunate

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 [MA200 trade name] is and what it is used for

[MA200 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 given by injection.

Malaria is caused by infection with a parasite called *Plasmodium*, spread by the bite of an infected mosquito. [MA200 trade name] is used 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 medicines to select the right medicine for your malaria treatment.

2. What you need to know before you are given [MA200 trade name]

[MA200 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 [MA200 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 [MA200 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.

Driving and using machines

[MA200 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

3. How [MA200 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, [MA200 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.

Very common side effects (may affect more than 1 in 10 people)

Low red blood cell counts (anaemia), changes in levels of blood cells called reticulocytes, damage to red blood cells that may happen up to one month after treatment has finished, especially in young children and visitors from areas without malaria

Common side effects (may affect up to 1 in 10 people):

Dizziness, altered ability to taste, headache, slow heart rate (bradycardia), low blood pressure, cough, runny nose, vomiting, pain in the belly (abdomen), cramps, diarrhoea increased levels of liver enzymes and a substance called bilirubin seen in blood tests, yellowing of the skin or eyes (jaundice), blood pigment in urine, reduced kidney function, joint and muscle pain, fever.

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

Loss of appetite, flushing, nausea (feeling sick), constipation, severe painful rashes with flu-like symptoms (Stevens-Johnson syndrome), itching, rashes, tiredness, pain at the injection site.

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

Breakdown of blood cells (immune haemolytic anaemia), altered electrical activity in the heart (QT prolongation), severe allergic reaction (anaphylaxis).

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 health care 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 [MA200 trade name]

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

Store below 30ºC. Keep the vial and ampoule in the provided carton to protect from light.

Do not refrigerate or freeze. Avoid excursions above 30ºC.

The reconstituted solution should be stored below 30ºC and should be used within one hour.

Do not use this medicine after the expiry date stated on label after 'EXP'.

Do not use this medicine if you notice description of the visible signs of deterioration 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 [MA200 trade name] contains

- The active ingredient of artesunate powder for injection is artesunate and no other excipients.
- The ingredients of arginine and sodium bicarbonate injection (solvent for reconstitution) are arginine, sodium bicarbonate, phosphoric acid (for pH adjustment) and water for injection.

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

What [MA200 trade name] looks like and contents of the pack

Artesunate powder for injection: clear colourless type I glass vial (7mL) with a type I grey halogenated butyl rubber stopper, crimped with a purple aluminium-plastic cap.

Arginine and sodium bicarbonate injection (solvent for reconstitution): clear colourless type I glass ampoule (6mL).

Pack size: A plastic (PVC) tray containing one vial of artesunate powder for injection, one ampoule of arginine and sodium bicarbonate injection. The tray is packed in an outer carton.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the local representative of the supplier.

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