

Artesunate 100mg+Mefloquine
(as hydrochloride) 200 mg Tablets,
(Cipla Ltd), MA079

WHOPAR part 3

December 2012
Section 6 updated: May 2023

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets*

Artesunate and mefloquine (as hydrochloride) 100/200 mg tablets

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, healthcare provider 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 you get side effects and they become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist

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1. WHAT ARTESUNATE/MEFLOQUINE 100/200MG FDC (FIXED DOSE COMBINATION) CIPLA TABLETS IS AND WHAT IT IS USED FOR

Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets contain artesunate and mefloquine. These belong to a group of medicines called antimalarials.

Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets are used for the treatment of acute uncomplicated malaria caused by a parasite called *Plasmodium falciparum*. It is also used in the setting of mixed infections with this and other types of malaria parasites.

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

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2. BEFORE YOU TAKE ARTESUNATE/MEFLOQUINE 100/200MG FDC (FIXED DOSE COMBINATION) CIPLA TABLETS

Do not take Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets

- If you are allergic (hypersensitive) to artesunate, artemisinin, mefloquine, quinine, quinidine or any of the other ingredients of Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets (listed in section 6).
- If you have been or are recovering from severe malaria.
- You are taking or have recently taken halofantrine or ketoconazole.

Take special care with Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets

Check with your doctor, healthcare provider or pharmacist before taking Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets if you:

- have heart problems such as abnormal heart beat, or an abnormal electrical signal called “prolongation of QT interval”
- have liver problems
- have taken mefloquine in the last two months
- are taking any other medicines to treat malaria
- have a history of seizures
- feel worse, or too unwell to eat and drink
- have thalassaemia, sickle cell anaemia or G6PD-deficiency

Taking other medicines

Please tell your doctor, healthcare provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins and herbal medicines.

Do not take this medicine and tell your doctor, healthcare provider or pharmacist you are taking:

- any other medicines to treat malaria
- medicines to treat heart problems
- medicines used to treat allergies or inflammation called “non-sedating antihistamines” such as terfenadine or astemizole.
- cisapride or metoclopramide (used to treat stomach problems).
- medicines used to treat depression / seizures such carbamazepine, phenytoin, or valproic acid.
- ketoconazole or other antifungal agents of the same group (triazoles).

Tell your doctor or healthcare provider if you are taking antibiotics (medicines used to treat infections), such as ampicillin, amoxicillin, tetracycline, fluoroquinolones (ciprofloxacin, ofloxacin or sparfloxacin). The doctor or healthcare provider will decide if Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets can be taken.

Keep a list of all the medicines you take. Show this list to your doctor, healthcare provider or pharmacist before you start a new medicine like Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets.

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Taking Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets with food and drink

Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets may be taken with or without food.

Pregnancy and Breastfeeding

Pregnancy

Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets may be used in the second and third trimester of pregnancy. In the first trimester Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets should be used only if this is the only treatment immediately available. The doctor or healthcare provider will advise you.

Breastfeeding

You may use Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets while breastfeeding.

Driving and using machines

Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets can cause dizziness and tiredness. If you experience such side-effects during or after treatment with Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets you should not drive, operate machinery or perform tasks that require a high degree of manual and/or psychomotor dexterity (such as cycling) for at least 3 weeks following use of Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets.

3. HOW TO TAKE ARTESUNATE/MEFLOQUINE 100/200MG FDC (FIXED DOSE COMBINATION) CIPLA TABLETS

Always take Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets exactly as your doctor has told you. They should be swallowed whole if possible.

How much to take:

Children weighing 18 up to 30 kg (7 up to 13 years old)

1 tablet daily for 3 days

Adults and adolescents weighing 30 kg and above (over 13 years old)

2 tablets daily for 3 days

Taking Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets

- If you feel worse or are too unwell to eat or drink, talk to your doctor or healthcare provider.
- If you vomit within 30 minutes of taking the tablets, take another dose. If in doubt, talk to your doctor or healthcare provider.
- If you vomit more than 30 minutes after taking the tablets, take half the recommended dose. If in doubt; talk to your doctor or healthcare provider.
- If you vomit this second dose, talk to your doctor or healthcare provider. A different antimalarial treatment may be given.
- If swallowing the tablet(s) whole is not possible:
 - Fill a teaspoon with clean water
 - Allow the tablet(s) to disintegrate in this water
 - Then fill the teaspoon with clean water again and administer.

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If you take more Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets than you should

If you accidentally take too many tablets, talk to your doctor or healthcare provider at once, or go to your nearest emergency unit. You may require medical attention. Remember to take the medicine with you, and show it to the doctor or the staff of the emergency unit. If you have run out of tablets, take the empty packaging along with you.

If you forget to take Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets

Try to make sure that you do not miss any dose. However, if you do forget to take a dose, take the missed dose as soon as you realise that you have forgotten it. Then take the next dose after the prescribed interval. Do not take a double dose to make up for a forgotten tablet. Make sure you take all three doses of this regimen.

If you stop taking Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets

Do not stop taking the medicine unless your doctor or healthcare provider tells you to. Always follow the instructions carefully, and complete the course of medication.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets can cause side effects, although not everybody gets them.

Very common side effects (greater than 1 in 10 patients treated):

- Vomiting
- Dizziness
- Palpitations (irregular heart beat)
- Sleep disorder

Common side effects include (greater than 1 in every 100 patients treated):

- Feeling sick (nausea)
- Headache
- Stomach pain
- Diarrhoea
- Decrease or loss of appetite
- Tiredness
- Muscle and joint pain
- Problems in hearing
- Recurrence of malaria
- Increase blood levels of bilirubin (turning eyes or skin yellow)

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Uncommon side effects (between 1 in 1,000 and 1 in 100 patients treated):

- Hallucinations (unreal visual perceptions)
- Inflammation of the liver (hepatitis)
- Blurred vision and other visual disturbances
- Itchiness / scratchiness

The following side effects have been reported in patients treated with other medicinal products containing either of the two components of Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets (artesunate or mefloquine), or combinations of both. However, frequency estimates for these effects are not available:

Anxiety (worry), abnormal dreams, confusion, and serious effects related to the nervous system and the psyche (fits, depressive syndrome, acute psychosis), allergic reactions and skin rashes (also serious forms with involvement of skin and mucous membranes, called Stevens-Johnson syndrome), hives, numbness, weakness, tremor, chills, mild changes in the electrical recording of the heart, heart rhythm disturbances, slow heart rate, rupturing of red blood cells (haemolysis), and increased levels of liver enzymes in the blood.

If you get side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist.

5. HOW ARTESUNATE/MEFLOQUINE 100/200MG FDC (FIXED DOSE COMBINATION) CIPLA TABLETS IS STORED

- Keep out of the reach and sight of children
- Do not store above 30°C
- Do not use Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. This will help protect the environment. Return any leftover tablets to your pharmacist.

6. FURTHER INFORMATION

What Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets contain

- The active substances are artesunate and mefloquine.
- The other ingredients are:
 - Tablet core: Croscarmellose sodium, magnesium stearate and microcrystalline cellulose.
 - Tablet coating: Indigo carmine aluminium lake (FD & C Blue #2), hypromellose, macrogol, polysorbate 80 and titanium dioxide.

What Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets look like and contents of the pack

Artesunate/Mefloquine 100/200mg FDC (Fixed Dose Combination) Cipla Tablets are blue, round, smooth, biconvex, film-coated tablets. The tablets should not be divided.

Aluminium-aluminium blister strip with 3 tablets.

A carton having one strip of 3 tablets and
a carton having 2 strips of 3 tablets.

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

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