

Artesunate 25mg+Mefloquine
(as hydrochloride) 50 mg Tablets,
(Cipla Ltd), MA078

WHOPAR part 3

December 2012
Section 6 updated: May 2023

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Artesunate and mefloquine (as hydrochloride) 25/50 mg Fixed Dose Combination (FDC) Cipla Tablets¹

Artesunate and mefloquine (as hydrochloride) 25/50 mg tablets

Read all of this leaflet carefully before you start giving 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 your child. Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If your child gets 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.

In this leaflet

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2. Before you give Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets
3. How to give Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets
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1. WHAT ARTESUNATE/MEFLOQUINE 25/50MG FDC (FIXED DOSE COMBINATION) TABLETS IS AND WHAT IT IS USED FOR

Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets contain artesunate and mefloquine. These belong to a group of medicines called antimalarials.

Artesunate/Mefloquine 25/50mg 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.

This product is intended for use in children. Safety information on use in adults is also provided.

¹ 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 GIVING ARTESUNATE/MEFLOQUINE 25/50MG FDC (FIXED DOSE COMBINATION) CIPLA TABLETS

Do not give Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets

- if the child is allergic (hypersensitive) to artesunate, artemisinin, mefloquine, quinine, quinidine or any of the other ingredients of Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets (listed in section 6).
- If the child has or is recovering from severe malaria.
- If the child is taking or has recently taken halofantrine or ketoconazole.

Take special care with Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets

Check with your doctor, healthcare provider or pharmacist before giving Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets if the child:

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

Taking other medicines

Please tell your doctor, healthcare provider or pharmacist if the child is taking or has recently taken any other medicines, including medicines obtained without a prescription, vitamins and herbal medicines.

Do not give this medicine and tell your doctor, healthcare provider or pharmacist if the child is 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 the child is 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 25/50mg FDC (Fixed Dose Combination) Cipla Tablets can be given.

Keep a list of all the medicines the child takes. Show this list to your doctor, healthcare provider or pharmacist before you start to give a new medicine like Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets.

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Giving Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets with food and drink

Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets may be given with or without food.

Pregnancy and Breastfeeding

Pregnancy

Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Tablets Cipla may be used in the second and third trimester of pregnancy. In the first trimester Artesunate/Mefloquine 25/50mg 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.

Breastfeeding

Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets may be used in breastfeeding.

Driving and using machines

Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets can cause dizziness and tiredness. Patients who experience such side-effects during or after treatment with Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets 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 25/50mg FDC (Fixed Dose Combination) Cipla Tablets .

3. HOW TO GIVE ARTESUNATE/MEFLOQUINE 25/50MG FDC (FIXED DOSE COMBINATION) CIPLA TABLETS

Always give Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets exactly as your doctor has told you. They should be swallowed whole if possible.

How much to give:

Children weighing 5 up to 9 kg (6 up to 12 months old)

1 tablet daily for 3 days

Children weighing 9 up to 18 kg (1 to 6 years old)

2 tablets daily for 3 days

Giving Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets

- if the child feels worse or is too unwell to eat or drink, talk to your doctor or healthcare provider.
- if the child vomits within 30 minutes of taking the tablet(s), give another dose. If in doubt, talk to your doctor or healthcare provider.
- If the child vomits more than 30 minutes after taking the tablet(s), give half the recommended dose. If in doubt; talk to your doctor or healthcare provider.
- If this second dose is vomited, 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 give more Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets than you should

If you accidentally give too many tablets, talk to your doctor or healthcare provider at once, or go to your nearest emergency unit. The child 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 give Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets

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

If you stop giving Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets

Do not stop giving 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 25/50mg 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 (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
- Increased blood levels of bilirubin (turning eyes or skin yellow)

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

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The following side effects have been reported in patients treated with other medicinal products containing either of the two components of Artesunate/Mefloquine 25/50mg 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 the child gets side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell the doctor, healthcare provider or pharmacist.

5. HOW ARTESUNATE/MEFLOQUINE 25/50MG 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 25/50mg FDC (Fixed Dose Combination) Cipla 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 25/50mg 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 25/50mg FDC (Fixed Dose Combination) Cipla Tablets look like and contents of the pack

Artesunate/Mefloquine 25/50mg 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/>