PATINET INFORMATION LEAFLET: INFORMATION FOR THE USER

Artesunate Amodiaquine Winthrop® 50/135 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, health care worker 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or health care worker.

In this leaflet:
1. What Artesunate Amodiaquine Winthrop is and what it is used for
2. Before you take Artesunate Amodiaquine Winthrop
3. How to take Artesunate Amodiaquine Winthrop
4. Possible side effects
5. How to store Artesunate Amodiaquine Winthrop
6. Further information

1. WHAT ARTESUNATE AMODIAQUINE WINTHROP IS AND WHAT IT IS USED FOR

This medicine is an antimalarial, i.e, a drug used to treat a certain type of malaria infection. Artesunate Amodiaquine Winthrop contains two antimalarial medicines, artesunate and amodiaquine, which work together to kill the malaria parasite (tiny organism that is found inside the red blood cells). Your doctor has found that you have malaria and so has prescribed Artesunate Amodiaquine Winthrop.

It is indicated only for the treatment of so called uncomplicated malarial attacks due to *Plasmodium falciparum* (a particular type of malaria parasite) against which the medicine is active.

For complete cure it is important that you complete the prescribed dose as advised by your doctor, pharmacist or health care worker.

2. BEFORE YOU TAKE ARTESUNATE AMODIAQUINE WINTHROP

Do not take Artesunate Amodiaquine Winthrop
- if you are allergic to artesunate, amodiaquine or any of the other ingredients of Artesunate Amodiaquine Winthrop (see section 6, What Artesunate Amodiaquine Winthrop contains),
- If you have ever had liver problems during treatment with amodiaquine,
- If you have ever suffered from sudden high fevers, shaking, severe sore throat or ulcers in the mouth (symptoms suggestive of harm to white blood cells) during treatment with amodiaquine.
- If you have an eye disease with damage to your retina.

If you have any doubt, it is essential to ask the advice of your doctor, pharmacist or health care worker.

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* * 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.
Take special care with Artesunate Amodiaquine Winthrop
This medicine may cause damage to the liver and/or blood that can sometimes be fatal. In case of marked asthenia (fatigue), gastrointestinal disturbances, (nausea, vomiting, abdominal pain), jaundice (dark urine, pale bowel motions), sore throat or mouth ulcers, stop the treatment and consult a doctor immediately; your doctor may need to take a blood sample.

Tell your doctor, pharmacist or health care worker, if you have used this or another amodiaquine-containing medicine very recently. Since you might then be more likely to experience side effects, special caution is warranted.

This medicine may cause abnormal movements of the head, tongue or neck (see section 4, Possible side effects). If these symptoms occur, stop the treatment and consult a doctor immediately. These symptoms are usually reversed by discontinuation of the treatment; however medical treatment of the symptoms may be necessary. Your doctor may recommend another antimalarial treatment.

Because caution should be exercised in some patients, it is important to inform your doctor if you have, or have ever had, any of the following:
- a problem with your heart rhythm or any other heart problem,
- a family history of heart rhythm problem or sudden death,
- low levels of potassium or magnesium in your blood,
- problems with your liver or kidneys.
If in doubt, do not hesitate to ask the advice of your doctor, pharmacist or health care worker.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines and Artesunate Amodiaquine Winthrop interfere with each other. Some of these medicines include:
- other medicines used to treat malaria,
- medicines used to treat an abnormal heart rhythm,
- medicines that can have side effects on your heart, including some medicines used to treat depression or mental illnesses, and some antibiotic medicines,
- medicines used to treat HIV/AIDS.

Pregnancy and breast-feeding
Do not use this drug during pregnancy without medical advice particularly during the first 3 months of pregnancy.
If you learn that you are pregnant during the treatment, take medical advice: your doctor is the only one to know if you can continue the treatment.
Breastfeeding can be considered after medical advice.
Generally, during pregnancy and breastfeeding, you should always ask the advice of your doctor, pharmacist or health care worker before using any drug.

Driving and using machines
If you are experiencing dizziness or fatigue after having taken this medicine, you should not drive vehicles or operate machinery.

3. HOW TO TAKE ARTESUNATE AMODIAQUINE WINTHROP 50/135 MG TABLETS
Always take Artesunate Amodiaquine Winthrop 50/135 mg Tablets exactly as your doctor has told you. You should check with your doctor, pharmacist or health care worker if you are not sure.
The dosage should be adjusted in accordance with the patient’s weight/age as listed in the following table:
<table>
<thead>
<tr>
<th>Weight range</th>
<th>On three consecutive days</th>
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<tbody>
<tr>
<td>≥9kg to &lt;18kg (1 to 5 years)*</td>
<td>50 mg artesunate + 135 mg amodiaquine/day (1 tablet Artesunate Amodiaquine Winthrop 50mg/135mg in one intake per day)</td>
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<tr>
<td>≥18kg to &lt;36kg (6 to 13 years)*</td>
<td>100 mg artesunate + 270 mg amodiaquine/day (2 tablets Artesunate Amodiaquine Winthrop 50mg/135mg in one intake per day)</td>
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<tr>
<td>≥ 36kg (14 years and above)*</td>
<td>200 mg artesunate + 540 mg amodiaquine/day (4 tablets Artesunate Amodiaquine Winthrop 50mg/135mg in one intake per day)</td>
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*If a weight-age mismatch occurs, dosing should be weight-based

With this product appropriate dose adjustments cannot be achieved for children weighing less than 9 kg. For these patients tablets containing less artesunate and amodiaquine are available.

For reducing the daily tablet count, patients weighing 18 kg and over (6 years of age or older) may take a product containing more artesunate and amodiaquine.

Ask the advice of your doctor, pharmacist or health care worker.

Artesunate Amodiaquine Winthrop Tablets should not be taken with a high-fat meal. Swallow the tablet with a drink of water.
For very young children or patients not able to swallow the tablets whole, the tablets should be crushed or dissolved in water before administration.
If you vomit within half an hour of taking the tablets, take another dose as soon as you can. Then, contact your doctor for a prescription for more tablets. Tell your doctor if you keep vomiting.

If you take more Artesunate Amodiaquine Winthrop Tablets than you should
If you accidentally take a lot more tablets than the doctor prescribed, contact a doctor or the nearest hospital emergency department immediately, or make sure that someone else contacts them for you. Headaches, dizziness, visual disturbances, circulatory collapse, convulsions, or abnormal movements of the head, tongue or neck, usually indicate an overdosage. If any of these symptoms occur, stop the treatment and consult a doctor immediately.

If you forget to take Artesunate Amodiaquine Winthrop Tablets
Try to make sure that you do not miss any dose. However, if you do forget 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.

If you stop taking Artesunate Amodiaquine Winthrop Tablets
To be effective the medicine must be taken regularly at the dose prescribed and for as long as your doctor has advised. The disappearance of fever or any other symptoms does not mean that you are completely cured. Any sensations of fatigue, nausea, vomiting might not be due to the drug but to the infection itself. Reducing or suspending your treatment would have no effect on these sensations or symptoms and would only delay your recovery.

If you have any further questions on the use of this product, ask your doctor, pharmacist or health care worker.
4. POSSIBLE SIDE EFFECTS

Like all medicines, Artesunate Amodiaquine Winthrop can cause side effects, although not everybody gets them.

Common side effects (affects 1 to 10 users in 100):
loss of appetite, difficulty sleeping, sleepiness, cough, nausea, abdominal pain, weakness, tiredness.

Uncommon side effects (affects 1 to 10 users in 1,000):
acute bronchitis, gastroenteritis, oral thrush, decrease in red blood cell count (anaemia), hypoglycaemia (low blood sugar), hallucination, tingling and numbness of the limbs, yellowing of the eye, dizziness, heart rhythm disorders, diarrhoea, vomiting, itching, rashes, swelling of the face, skin disorders, joint pain, swelling of the limbs (oedema), fever.

Side effects that may be linked to amodiaquine, one of the active ingredients of Artesunate Amodiaquine Winthrop: low number of white blood cells (which can make you more prone to infections), potentially severe disturbances of liver function, eye disorders - slate-grey pigmentation, especially of the fingers and mucous membranes, nervous system and muscle impairment.

During post-marketing experience the following additional side effects have been reported (frequency not known): headache, cold, flu, rhinitis, shivering, sore throat, enlargement of the spleen, convulsion, yellowing of the skin, allergic reaction. For some of these events it is unclear whether they are related to amodiaquine/artesunate or to the underlying malaria disease. Also, side effects known as extrapyramidal symptoms have been reported. These symptoms may include: abnormal movements of the head, tongue or neck (e.g. facial spasms, tongue protrusion, difficulties in speaking) and generalized rigidity, even after administration of a single dose.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor, pharmacist or health care worker.

5. HOW TO STORE ARTESUNATE AMODIAQUINE WINTHROP

Keep out of the reach and sight of children.

Store this medicine in its original package below 30°C.

Do not use Artesunate Amodiaquine Winthrop after the expiry date which is stated on the blister and the outer packaging after EXP. The expiry date refers to the last day of that month.

The tablets may be mottled but it does not alter the safety and effectiveness of the product.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
6. FURTHER INFORMATION

What Artesunate Amodiaquine Winthrop contains
The active ingredients are artesunate and amodiaquine (as hydrochloride).
The other ingredients are: Croscarmellose sodium, Povidone K30, Silicia colloidal anhydrous, Microcrystalline cellulose, Magnesium stearate, Calcium carbonate DC CS90 (calcium carbonate and maize starch).

What Artesunate Amodiaquine Winthrop looks like and contents of the pack
Artesunate Amodiaquine Winthrop is a round bilayer tablet, with score line: one layer is yellow coloured, the other one is white to slightly yellow.
Artesunate Amodiaquine Winthrop 50mg/135mg is engraved on one side “AS” and on the other side “50”.
Artesunate Amodiaquine Winthrop 50mg/135mg is presented in:
- Carton box of 1 blister pack of 3 tablets.
- Carton box of 25 blister packs of 3 tablets each.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Supplier and Manufacturer

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>Sanofi-aventis</td>
<td>Maphar, Km 10, Route Côtière 111</td>
</tr>
<tr>
<td>9, rue du Président Allende 94250 Gentilly – France</td>
<td>Quartier industriel Zenata, Ain Sebaâ</td>
</tr>
<tr>
<td>Tel : +33 (0)1 41 24 70 00</td>
<td>20250 Casablanca</td>
</tr>
<tr>
<td>Fax : +33 (0)1 41 24 58 48</td>
<td>Morocco</td>
</tr>
<tr>
<td></td>
<td>Sanofi-aventis Maroc, Route de Rabat R.P.1-</td>
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<tr>
<td></td>
<td>BP2611- Ain Sebaâ</td>
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<td></td>
<td>20250 Casablanca</td>
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<td>(for batch release)</td>
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For any information about this medicinal product, please contact the supplier.

This leaflet was last approved in September 2012

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