PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Apmod 50/35*

Artesunate/amodiaquine (as hydrochloride) 50mg/135mg tablets

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 any further questions, ask your doctor, health care provider or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. WHAT APMOD 50/135 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. Apmod 50/135 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 Apmod 50/135. 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 provider.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE APMOD 50/135

Do not take Apmod 50/135

- if you are allergic to amodiaquine, artesunate, or any of the other ingredients of Apmod 50/135 (see section 6, "What Apmod 50/135 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 provider.

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

Warnings and precautions

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 provider, 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,
- 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 provider.

Other medicines and Apmod 50/135

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines and Apmod 50/135 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 provider 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 APMOD 50/135

Always take Apmod 50/135 tablets exactly as your doctor has told you. You should check with your doctor, pharmacist or health care provider if you are not sure. The dosage should be adjusted in accordance with the patient's weight/age as listed in the following table:

Weight range (approximate age range)	**On three consecutive days**
≥9kg to <18kg (1 to 5 years)*	50 mg artesunate + 135 mg amodiaquine/day (1 tablet of Apmod 50/135 in one intake per day)
≥18kg to <36kg (6 to 13 years)*	100 mg artesunate + 270 mg amodiaquine/day (2 tablets of Apmod 50/135 in one intake per day)
≥ 36kg (14 years and above)*	200 mg artesunate + 540 mg amodiaquine/day (4 tablets of Apmod 50/135 in one intake per day)

*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 year of age or older) may take a product containing more amodiaquine and artesunate. Ask the advice of your doctor, pharmacist or health care provider.

Apmod 50/135 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 may be crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.

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 Apmod 50/135 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 over dosage. If any of these symptoms occur, **stop the treatment and consult a doctor immediately. If you forget to take Apmod 50/135**
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 Apmod 50/135

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 provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Apmod 50/135can 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 Apmod 50/135: 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 provider.

5. HOW TO STORE APMOD 50/135

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

Store below 30°C.

Do not use Apmod 50/135 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Apmod 50/135 contains

The active ingredients are 50 mg artesunate and 135 mg amodiaquine (as hydrochloride).

The other ingredients are: calcium carbonate, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose and povidone.

What Apmod 50/135 looks like and contents of the pack

Apmod 50/135 is a circular, bilayered, bevelled edged tablet. One layer is yellow in colour with score-line and the other layer is white to slightly yellow. The tablet is debossed with 'A' on one side of the score-line and '2' on the other side of the score-line.

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

Carton containing 1 blister (Alu-OPA/Alu/PVC) of 3 tablets. Pack size: 1x3

Carton containing 25 blisters (Alu-OPA/Alu/PVC) of 3 tablets each along with 25 patient information leaflets. Pack size: 25x3

Supplier and Manufacturer

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For any 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 https://extranet.who.int/prequal