

PACKAGE LEAFLET: INFORMATION FOR THE USER

Avloclor[®] 250 mg Tablets chloroquine phosphate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Avloclor is and what it is used for
2. What you need to know before you take Avloclor
3. How to take Avloclor
4. Possible side effects
5. How to store Avloclor
6. Contents of the pack and other information

1. What Avloclor is and what it is used for

Avloclor contains a medicine called chloroquine phosphate. This belongs to a group of medicines called ‘anti-malarials’.

‘Anti-malarials’ can be taken in certain parts of the world to help prevent malaria. This is a serious disease spread by infected mosquitoes. Avloclor will give some degree of protection (prophylaxis) against malaria in certain countries.

Medicines to help prevent malaria (malaria prophylaxis) are recommended for:

- People travelling to countries where malaria occurs.
- People living in malaria areas who are not immune to malaria.

These people have little or no immunity to malaria, so they are at risk of severe attacks.

You must get medical advice on which anti-malarial medicines to take. You must ask your doctor or pharmacist if Avloclor is suitable for the part of the world that you are visiting. In some countries you may have to take Avloclor with another medicine for maximum protection.

Avoiding mosquito bites

When you are taking this medicine to prevent malaria, you should also reduce the chances of being bitten by mosquitoes.

- Wear light-coloured, long-sleeved clothing and long trousers when you are outside after sunset.
- Use insect repellent creams or sprays on parts of your body not covered by clothing.

- Sleep in a properly screened room or under a mosquito net.
- Spray to kill any mosquitoes that may have entered rooms in spite of screening.

Signs of malaria

No medicine can be guaranteed to protect against malaria in every case. **If you have a high temperature (fever) during your visit to a malaria area, or up to a year after returning home, you should suspect malaria.** Contact a doctor straight away and let him or her know that you have visited a malaria area.

2. What you need to know before you take Avloclor

Do not take Avloclor if:

- You are allergic to chloroquine phosphate or any of the other ingredients of Avloclor (see Section 6: Contents of the pack and other information).
- You are taking a medicine called amiodarone (used to control the heart rate). Avloclor may increase the risk of uneven heart beats (cardiac arrhythmias) when it is taken at the same time as amiodarone. Check with your doctor or pharmacist if you are not sure.

Warnings and precautions

Check with your doctor or pharmacist before taking your medicine if:

- You have ever had epilepsy, convulsions or fits.
- You have ever had problems with your liver or kidneys.
- You have ever been told that you have a rare disease of the blood pigment called ‘porphyria’ or anyone in your family has it. This is because Avloclor may cause severe symptoms of porphyria, particularly if you drink alcohol.
- You have a scaly condition of the skin called psoriasis.
- You have a muscle problem called ‘myasthenia gravis’. Avloclor can increase the symptoms of this condition. It can also reduce the effect of medicines used to treat this condition (neostigmine and pyridostigmine).
- You have a blood problem called ‘glucose-6-phosphate dehydrogenase deficiency’. Avloclor may damage blood cells in people with this blood condition.

Chloroquine can cause lowering of the blood glucose level. Please ask your doctor to inform you of signs and symptoms of low blood glucose levels. A check of the blood glucose level may be necessary.

Chloroquine may cause heart rhythm disorders in some patients: caution should be taken when using chloroquine, if you were born with or have family history of prolonged QT interval, if you have acquired QT prolongation (seen on ECG, electrical recording of the heart), if you have heart disorders or have a history of heart attack (myocardial infarction), if you have salt imbalance in the blood (especially low level of potassium or magnesium, see section “Other medicines and Avloclor”).

If you experience palpitations or irregular heart beat during the period of treatment, you should inform your doctor immediately. The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed.

Some people being treated with chloroquine can experience mental health problems such as irrational thoughts, hallucinations, feeling confused, aggressiveness, paranoia, feeling depressed

or have thoughts of self-harm or suicide, even those who have never had similar problems before. If you or others around, you notice any of these side effects (see section 4) seek medical advice straight away.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Avloclor.

If you go into hospital, tell the medical staff that you are taking Avloclor.

If you live in a country where malaria occurs, you may already be slightly immune to the disease. You must ask a doctor or pharmacist for advice before you take anti-malarial medicines.

Other medicines and Avloclor

Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Amiodarone (used to control heart rate) must not be taken at the same time as Avloclor (see section 2: what you need to know before you take Avloclor).

Tell your doctor or pharmacist if you are taking any of the following medicines. This is because Avloclor may affect the amount of these medicines in your blood.

- Praziquantel (used to treat infections of the bowel and bladder caused by parasites).
- Ciclosporin (mainly used by transplant patients but also used to treat rheumatoid arthritis and psoriasis).
- Anti-convulsant medicines (used to prevent convulsions or fits).
- Digoxin (used to treat heart problems).

Also tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines known to affect the rhythm of your heart. This includes medicines used for abnormal heart rhythm (antiarrhythmics), for depression (tricyclic antidepressants) for psychiatric disorders (antipsychotics), for bacterial infections or against malaria (e.g. halofantrine).
- Azithromycin, clarithromycin, or erythromycin (antibiotics used for treating infections). Taking these medicines at the same time as chloroquine may increase the chance of you getting side effects that affect your heart.
- Mefloquine (taken to prevent malaria) may increase the risk of convulsions or fits when taken at the same time as Avloclor.
- Medicines used to treat epilepsy, as Avloclor may reduce their effectiveness.
- Agalsidase (used to treat Fabry Disease), as Avloclor may reduce its activity.
- Cimetidine (used to treat stomach problems). This medicine affects how Avloclor is broken down by your body and may affect the amount of Avloclor in your blood.
- Levothyroxine (thyroid medicine).
- Medicines like kaolin (used for diarrhoea) which are called 'adsorbents'.
- Antacid medicines (aluminium, calcium and magnesium salts that are used to treat heartburn or indigestion).

Adsorbents and antacid medicines may reduce the amount of Avloclor absorbed from your gut. This may mean that the full dose of Avloclor is not absorbed into your body and it will not work properly. Therefore, you should take these medicines at least four hours before or after taking your Avloclor dose.

Some medicines (for example, ciprofloxacin, cimetidine, omeprazole, pyrimethamine) may increase the amount of Avloclor in your body and this can cause side effects. It is important that you do not take any additional medicines (either prescribed or non-prescribed) before speaking to your doctor.

If you need a vaccination against rabies, make sure you have it before you start your anti-malarial medicine. If you have your rabies injection at the same time as taking your anti-malarial medicine, your rabies vaccine might not work so well.

Pregnancy

If you are pregnant or may become pregnant, **talk to a doctor or pharmacist:**

- before you take Avloclor,
- before you take any medicine to prevent malaria,
- and before you go to a country where there is malaria.

Breast-feeding

- If you are breast-feeding, talk to a doctor or pharmacist before taking Avloclor.
- Although Avloclor passes into the breast milk, the amount is not enough to protect your baby from malaria. Therefore, your baby will still need to be given anti-malarial medicines. Ask your doctor or pharmacist who will be able to give you advice.

Driving and using machines

Sometimes Avloclor causes blurred eyesight or makes it difficult to focus your eyes. If this happens to you, do not drive or use any tools or machines.

3. How to take Avloclor

Always take Avloclor exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

When to start taking your medicine

- Start taking this medicine one week before you enter the malaria area.
- You must continue to take it during your stay.
- You must keep taking this medicine for **4 weeks after leaving the malaria area.**

Adults and children over 14 years

- Take two Avloclor tablets once a week on the same day each week.

Elderly people

- If you are an elderly person your doctor may suggest that you have blood tests. Your doctor may also decide to give you a different dose.

Children

Do not give Avloclor to children under 1 year of age. For children over 1 year of age, the dose depends on the child's age.

- **Ages 1 to 4 years:** Take half an Avloclor tablet once a week (on the same day each week).
- **Ages 5 to 8 years:** Take one Avloclor tablet once a week (on the same day each week).
- **Ages 9 to 14 years:** Take one and a half Avloclor tablets once a week (on the same day each week).

How to take your tablets

- Take the tablet(s) after food.
- Swallow the tablet(s), or part tablets, whole with a drink of water.

If you take more Avloclor tablets than you should

If you accidentally take more Avloclor tablets than you should, tell a doctor straight away. The following effects may happen: heart problems – leading to uneven heart beats.

If you forget to take your Avloclor tablets

- If you forget to take a dose of Avloclor, take it as soon as you remember.
- Then wait for 7 days before you take the next dose of Avloclor.
- Carry on taking your Avloclor tablets each week, on this new day of the week.

Stopping Avloclor

Only stop taking Avloclor four weeks after leaving the malaria area or if your doctor tells you to.

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

4. Possible side effects

Like all medicines, Avloclor can cause side effects, although not everybody gets them.

Serious side effects

If you experience any of the following side effects, stop taking Avloclor and get medical help or contact your doctor straight away.

- Allergic reactions including difficulty breathing, swelling of the face, lips, tongue or throat which may cause difficulty in swallowing and an itchy rash (similar to nettle rash or hives)
 - A severe rash with blisters or peeling of the skin and possibly blisters in the mouth and nose.
 - Seeing, feeling or hearing things that are not there (hallucinations) (rare).
 - Cardiac muscle disease (cardiomyopathy) which may be fatal in case of high-dose long-term use. See section 2, warnings and precautions (rare).
 - Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG). See section 2, Warnings and precautions (frequency not known).
 - Liver problems which may cause yellowing of your skin or the whites of your eyes.
- If you are taking Avloclor for a long time, your doctor may suggest that you have blood tests to check how well your liver is working (rare).
- Inflammation of the lungs causing a condition known as diffuse parenchymal lung disease.

If you develop serious breathlessness or worsening of breathlessness seek prompt medical advice.

- Convulsions or fits.
- Some or complete loss of eyesight.
- Changes to the retina of your eye (retinopathy) or to the cornea. This can lead to 'patchy' eyesight.
- A rash caused by the medicine associated with an increase in the number of white blood cells (that may show up in blood tests) and symptoms involving the whole body. You may notice some or all of the following symptoms: a skin rash and fever, swelling of the face, tender generalized swollen or enlarged lymph nodes, or other symptoms suggesting involvement of other body organs including the liver, kidney or lung (such as yellowing of the skin or eyes, urinary problems, breathlessness).
- A reduced number of blood cells. This can make you bruise more easily, get serious infections, have sudden bleeding or feel very tired or breathless. If you are taking Avlocor for a long time, your doctor may suggest that you have blood tests.

Other possible side effects (frequency not known)

When Avlocor is used to prevent or suppress malaria, these are generally not serious. If Avlocor is used for a long time, they can be more serious.

Heart

- Changes in the way your heart works (known as 'electrocardiographic changes').
- Low blood pressure. This may make you feel faint or dizzy.

Nervous system

- Headache.
- Feeling dizzy or light-headed.
- Involuntary muscle movements or spasms.

Behaviour

- Insomnia.
- Mood changes or other effects on behaviour. These include feeling depressed or having thoughts of self-harm or suicide, feeling anxious, feeling confused, having irrational thoughts, paranoia, aggressiveness, sleep disorders, agitation, feeling elated or overexcited, lack of concentration.

Skin

- Skin rash, including a scaly rash (psoriasis) or itch.
- Peeling skin.
- Discolouration of the skin or mucous membranes (such as the inside of your mouth).
- Being sensitive to sun light which may require medical treatment.
- The appearance of small fluid filled bumps on the skin.

Hair

- Changes in hair colour.
- Hair loss.

Eyes

- Blurred eyesight.
- Problems with your colour vision.
- Difficulty in focussing your eyes.
- Double vision.

If you are taking Avloclor for a long time, your doctor may suggest that you have eye tests.

Ears

- Hearing loss.
- Ringing in the ears (tinnitus).

Stomach and gut

- Stomach upsets, feeling sick (nausea), being sick (vomiting), diarrhoea or stomach cramps.

Other

- Weakening of your muscles (neuromyopathy and myopathy).
- Lowering of the blood glucose level.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Avloclor

- Keep this medicine out of the sight and reach of children. . Your medicine could harm them.
- Do not store your medicine above 30°C.
- Protect the tablets from light and moisture.
- Keep the tablets in the container they came in.
- Do not take Avloclor after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

6. Contents of the pack and other information

What Avloclor Tablets contain

- The active substance in Avloclor Tablets is chloroquine phosphate. Each tablet contains 250 mg of chloroquine phosphate (equivalent to 155 mg of chloroquine base).
- The other ingredients are magnesium stearate (E572) and maize starch.

What Avloclor Tablets look like and contents of the pack

Avloclor Tablets are white and round. They have a break line on one side and the letter 'A' either side of the line. Avloclor Tablets come in packs of 20 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Avlocloclor Tablets is held by Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Avlocloclor Tablets are manufactured by AndersonBrecon (UK) Limited, Wye Valley Business Park, Brecon Road, Hay-on-Wye, Hereford HR3 5PG UK.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Avlocloclor Tablets**

Reference number 16853/0143

This is a service provided by the Royal National Institute of blind people.

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