

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paludrine®/Avloclor® Anti-malarial Travel Pack

proguanil hydrochloride tablets (100 mg) and chloroquine phosphate tablets (250 mg)

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 Paludrine/Avloclor Anti-malarial Travel Pack is and what it is used for
2. What you need to know before you use your Anti-malarial Travel Pack
3. How to use your Anti-malarial Travel Pack
4. Possible side effects
5. How to store your Anti-malarial Travel Pack
6. Contents of the pack and other information

1. What Paludrine/Avloclor Anti-malarial Travel Pack is and what it is used for

The name of your medicine is 'Paludrine/Avloclor Anti-malarial Travel Pack'. It is referred to as 'Anti-malarial Travel Pack' in the rest of this leaflet.

Your Anti-malarial Travel Pack contains two types of tablets:

- The Paludrine tablets contain a medicine called proguanil hydrochloride.
- The Avloclor tablets contain a medicine called chloroquine phosphate.

Both medicines belong to a group of medicines called 'anti-malarials'.

'Anti-malarials' can be used in certain parts of the world to help prevent malaria. This is a serious disease spread by infected mosquitoes. Your Anti-malarial Travel Pack will give some degree of protection (prophylaxis) against malaria in certain countries. It can be used when it is necessary to take more than one type of medicine at the same time to help prevent malaria.

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 this Anti-malarial Travel Pack is suitable for the part of the world that you are visiting.

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.

If you have a high temperature

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 use your Anti-malarial Travel Pack

Do not use this Anti-malarial Travel Pack if:

- You are allergic to proguanil hydrochloride, chloroquine phosphate or any of the other ingredients in the tablets (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.
- 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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using your Anti-malarial Travel Pack.

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 your Anti-malarial Travel Pack”).

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.

If you go into hospital, tell the medical staff that you are taking both Paludrine and 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 your Anti-malarial Travel Pack

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).
- Cyclosporin (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:

- Warfarin or other medicines used to prevent blood clots. Paludrine may increase the effect of these 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).
- Mefloquine, taken to prevent malaria may increase the risk of convulsions or fits when taken at the same time as Avloclor.
- Levothyroxine (thyroid medicine)
- Medicines used to treat epilepsy, as Avloclor may reduce their effectiveness.
- Agalsidase (used to treat Fabry Disease), as Avloclor may reduce its activity.
- Boosted protease-inhibitors (medicines used in the treatment of viral infections, such as HIV/AIDS), as these may alter the levels of Paludrine in your body.
- 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.
- Medicines like kaolin (used for diarrhoea) which are called 'adsorbents'.
- Antacids (aluminium, calcium and magnesium salts that are used to treat heartburn or indigestion).

Antacids 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 your antacid dose 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.

If you know you are to have a live oral typhoid vaccination, you must tell your doctor beforehand as your treatment with Paludrine might need to be adjusted.

Pregnancy

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

- before you use this Anti-malarial Travel Pack,
- before you take any medicine to prevent malaria,
- and before you go to a country where there is malaria.

Paludrine can affect the levels of folic acid in the body, therefore pregnant women taking Paludrine should be given supplements that contain folic acid.

Breast-feeding

- If you are breast-feeding, talk to a doctor or pharmacist before using your Anti-malarial Travel Pack.
- Although Paludrine and Avloclor pass 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 tablets cause blurred eyesight or make it difficult to focus your eyes. If this happens to you, do not drive or use any tools or machines.

3. How to use your Anti-malarial Travel Pack

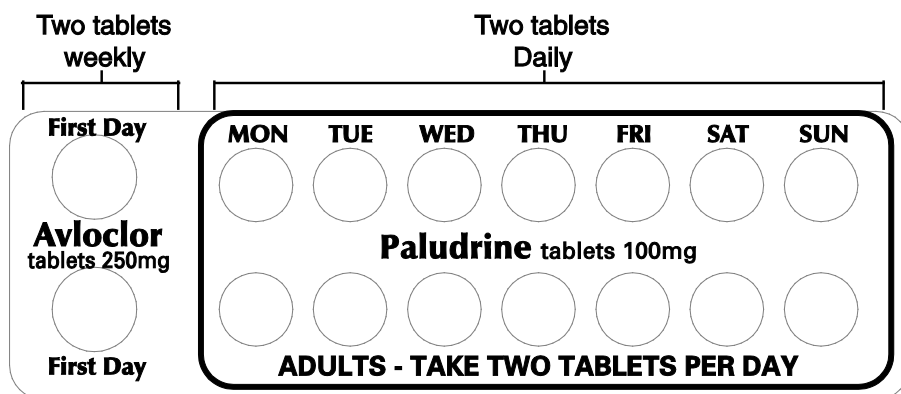
If this medicine is from your doctor or pharmacist, take it exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or you are not sure, ask your doctor or pharmacist.

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.
- **And** take two Paludrine tablets daily, at the same time each day.



Children

Do not use this Anti-malarial Travel Pack in 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) **and** take half a Paludrine tablet daily (at the same time each day).
- **Ages 5 to 8 years:** Take one Avloclor tablet once a week (on the same day each week) **and** take one Paludrine tablet daily (at the same time each day).
- **Ages 9 to 14 years:** Take one and a half Avloclor tablets once a week (on the same day each week) **and** take one and a half Paludrine tablets daily (at the same time each day).

How to take your tablets

- Take the tablet(s) after food.
- Swallow the tablet(s), or part tablets, whole with a drink of water.
- For a young child, the tablet(s) may be given crushed in milk, honey or jam.

If you take more Paludrine or Avloclor tablets than you should

If you accidentally take more Paludrine or Avloclor tablets than you should, tell a doctor straight away. Show any left-over medicines or the empty packet to the doctor. The following effects may happen if you take more Avloclor tablets than you should: heart problems – leading to uneven heart beats.

If you forget to take your Paludrine tablets

- If you forget to take a dose of Paludrine, take it as soon as you remember. However, if it is nearly time for the next dose of Paludrine, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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 your Anti-malarial Travel Pack

Only stop using your Anti-malarial Travel Pack 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, your Anti-malarial Travel Pack can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, **stop using your Anti-malarial Travel Pack and get medical help or contact your doctor straight away.** The signs may include:

- Difficulty in breathing.
- Swelling of the face, lips, tongue or throat which may cause difficulty in swallowing.
- An itchy rash (similar to nettle rash or hives).

Other possible side effects

Heart

- Changes in the way your heart works (known as ‘electrocardiographic changes’).
- Low blood pressure. This may make you feel faint or dizzy.
- Cardiac muscle disease (cardiomyopathy) which may be fatal in case of high-dose long-term use (rare). See section 2, Warnings and precautions.
- Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG). See section 2, Warnings and precautions.

Lungs

- 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.

Mouth

- Mouth ulcers.
- Inflamed mouth.

Nervous system

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

Behaviour

- Insomnia
- Mood changes or other effects on behaviour. These include feeling: depressed, confused, anxious, or rarely, seeing, feeling or hearing things that are not there (hallucinations).

Skin

- Skin rash, including a scaly rash (psoriasis) or itch, which sometimes causes swelling of the affected area.
- Peeling or scaly skin.
- A severe rash with blisters or peeling of the skin and possibly blisters in the mouth and nose.

- 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 (sometimes reversible).

Eyes

- Blurred eyesight.
- Some or complete loss of eyesight.
- Problems with your colour vision.
- Difficulty in focussing your eyes.
- Double vision.
- Changes to the retina of your eye(s) leading to 'patchy' eyesight (retinopathy).

If you are using your Anti-malarial Travel Pack for a long time, your doctor may suggest that you have eye tests.

Ears

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

Blood

- A reduced number of blood cells. This can lead to easy or unexplained bruising, serious infections, sudden bleeding or feeling very tired, weak or breathless.

If you are using your Anti-malarial Travel Pack for a long time, your doctor may suggest that you have blood tests.

Liver

- Liver problems which may cause yellowing of your skin or the whites of your eyes.

If you are using your Anti-malarial Travel Pack for a long time, your doctor may suggest that you have blood tests to check how well your liver is working.

Stomach and gut

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

Other

- High temperature (fever).
- Inflammation of blood vessels, which can cause tiredness, weakness, loss of appetite, rash, ulcers, blood shot eyes, pain in the joints, breathlessness and weight loss.
- Weakening of your muscles (neuromyopathy and myopathy).
- 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).

- 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your Anti-malarial Travel Pack

- 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 use your Anti-malarial Travel Pack 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 Paludrine/Avloclor Anti-malarial Travel Pack contains

Paludrine/Avloclor Anti-malarial Travel Pack contains two types of tablets, Paludrine tablets and Avloclor tablets.

Paludrine tablets:

- The active substance in Paludrine tablets is proguanil hydrochloride. Each tablet contains 100 mg of proguanil hydrochloride.
- The other ingredients are calcium carbonate, gelatin, magnesium stearate (E572) and maize starch.

Avloclor tablets:

- 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 Paludrine/Avloclor Anti-malarial Travel Pack looks like and contents of the pack

Paludrine tablets are white and round. They have a break line on one side with the letter 'P' either side of the line.

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

Paludrine/Avloclor Anti-malarial Travel Pack contains 112 tablets (98 Paludrine tablets and 14 Avloclor tablets).

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Paludrine/Avloclor Anti-malarial Travel Pack is held by Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Paludrine/Avloclor Anti-malarial Travel Pack is 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	Paludrine/Avloclor Anti-malarial Travel Pack
Reference number	16853/0145

This is a service provided by the Royal National Institute of Blind People.

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