

## **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 because it contains important information for you.**

This medicine is available without prescription. However, you still need to use your Paludrine/Avloclor Anti-malarial Travel Pack carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Paludrine/Avloclor Anti-malarial Travel Pack is and what it is used for
2. Before you use your Anti-malarial Travel Pack
3. How to use your Anti-malarial Travel Pack
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### **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. 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: Further 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.

### **Take special care with this medicine**

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.

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.

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.

### **Taking other medicines**

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

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:

- Warfarin or other medicines used to prevent blood clots. Paludrine may increase the effect of these medicines.
- Other medicines used to prevent malaria, such as mefloquine. There is a risk of convulsions or fits when these medicines are taken at the same time as Avloclor.
- 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.

### **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.

### **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

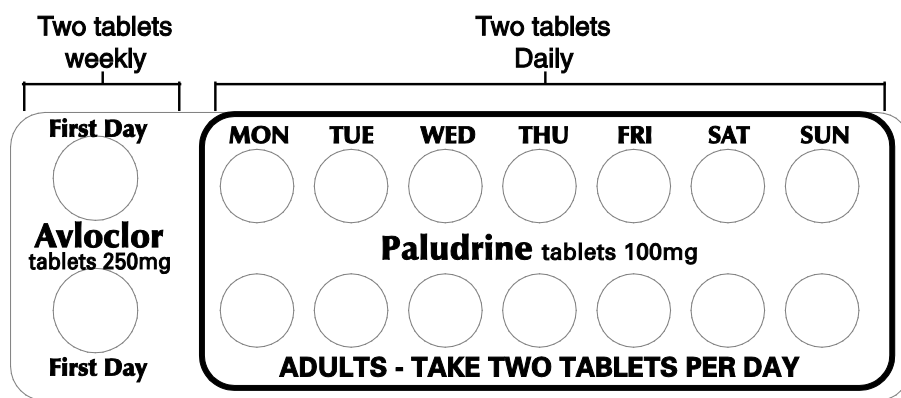
If this medicine is from your doctor or pharmacist, take it exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or you are not sure, ask your doctor or pharmacist.

#### 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 take more Paludrine or Avloclor tablets than you should, talk to a doctor or go to a hospital straight away.

#### 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**

The more common side effects are:

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

The following side effects occur infrequently, or may occur if you use your Anti-malarial Travel Pack for a long period of time:

#### **Mouth**

- Mouth ulcers.
- Inflamed mouth.

#### **Nervous system**

- Feeling dizzy or light-headed.
- Convulsions or fits.
- Mood changes or other effects on behaviour. These include feeling 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.
- 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.

### **Hair**

- Changes in hair colour.
- Hair loss (sometimes reversible).

### **Eyes**

- Blurred eyesight.
- Some or complete loss of eyesight.
- 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 make you bruise more easily, get serious infections, or feel very tired or breathless.

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

### **Heart**

- Changes in the way your heart works (known as 'electrocardiographic changes').
- Low blood pressure. This may make you feel faint or dizzy.
- Weakening or change in the heart muscle (cardiomyopathy). This may make you feel tired or short of breath.

### **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.

### **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.

### **Other**

- High temperature (fever).
- Weakening of your muscles (neuromyopathy).
- 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](http://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 your medicine in a safe place where children cannot see or reach it. 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. Further 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 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 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:

<b>Product name</b>	<b>Paludrine/Avloclor Anti-malarial Travel Pack</b>
Reference number	16853/0145

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

This leaflet was last revised in November 2013

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