

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paludrine® 100 mg tablets proguanil hydrochloride

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

1. What Paludrine is and what it is used for

Paludrine contains a medicine called proguanil hydrochloride. This belongs 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. Paludrine will give some degree of protection (prophylaxis) against malaria in certain countries. Paludrine can also be prescribed by a doctor to help suppress some types of 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 Paludrine is suitable for the part of the world that you are visiting. In some countries you may have to take Paludrine 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 Paludrine

Do not take Paludrine if:

- You are allergic (hypersensitive) to proguanil hydrochloride or any of the other ingredients of this medicine (see Section 6: Contents of the pack and other information).

Warnings and precautions

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

- You have ever had problems with your kidneys. This is because your doctor may give you a lower dose of Paludrine.

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 Paludrine

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.

In particular, 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.
- Antacids (aluminium, calcium and magnesium salts that are used to treat heartburn or indigestion). Antacids may reduce the amount of Paludrine absorbed from your gut. This may mean that the full dose of Paludrine is not absorbed into your body and it will not work properly. Therefore, you should take your antacid dose at least two hours before or after taking your Paludrine dose.
- 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.

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 take Paludrine,
- 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 taking Paludrine.
- Although Paludrine 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

Paludrine is not likely to affect you being able to drive or use any tools or machines.

3. How to take Paludrine

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. If this is not possible, start taking this medicine at least two days 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 tablets daily.

Children

- **Under 1 year (including babies who are being breast-fed):** Take a quarter of a Paludrine tablet daily.
- **Ages 1 to 4 years:** Take half a Paludrine tablet daily.
- **Ages 5 to 8 years:** Take one Paludrine tablet daily.
- **Ages 9 to 14 years:** Take one and a half Paludrine tablets daily.

How to take your tablets

- Take the tablet(s) at the same time each day.
- 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 tablets than you should

If you take more Paludrine tablets than you should, talk to a doctor or go to a hospital straight away. Show any left-over medicines or the empty packet to the doctor.

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.

Stopping Paludrine

Only stop taking Paludrine 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, Paludrine can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, **stop taking Paludrine 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

Stomach and gut

- Stomach upsets, diarrhoea, constipation. These usually improve as treatment continues.

Mouth

- Mouth ulcers.
- Inflamed mouth.

Skin

- Skin reactions, including itching, peeling and rash, sometimes with swelling of the affected area.

Hair

- Hair loss (sometimes reversible).

Blood

- If you have kidney problems, Paludrine may cause changes to your blood.
- A reduced number of blood cells. This can lead to easy or unexplained bruising, bleeding, serious infections, or feeling very tired, weak or breathless.

Liver

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

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.

Do not be concerned by this list of possible side effects. You may not get any of them.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse 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 Paludrine

- 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 take Paludrine 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 Tablets contain

- 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.

What Paludrine Tablets look 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.

Paludrine Tablets come in packs of 98 tablets.

Marketing Authorisation Holder and Manufacturer

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

Paludrine 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	Paludrine Tablets
Reference number	16853/0144

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

This leaflet was last revised March 2015

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