NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

# Patient Group Direction For The Supply Of Medicines Included In The Malaria Prophylaxis PGD Formulary By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

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|---|---|---|
| **Lead Author:**<br>Medicines Management Specialist Nurse NHSG | **Consultation Group:**<br>See relevant page in the PGD | **Approver:**<br>NoS PGD Group<br><br>**Authorisation:**<br>NHS Grampian |

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| **Signature:**<br>  | | **Signature:**<br>  |

| | | |
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| **NoS Identifier:**<br>NoS/PGD/MalariaF/ MGPG1255 | **Review Date:**<br>June 2024<br><br>**Expiry Date:**<br>June 2025 | **Date Approved:**<br>June 2022 |

**NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.**

**Uncontrolled when printed**

**Version 1**

**Revision History:**

| | | |
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| **Reference and approval date of PGD that has been adapted and/or superseded** | New PGD adapted from NHSG PGDs:<br>Atovaquone/Proguanil/MGPG968<br>Doxy_mal/MGPG946<br>PGD_Mefloquine_MGPG952 | |
| **Date of change** | **Summary of Changes** | **Section heading** |
| April 2022 | New PGD | |

**NoS Identifier:** NoS/PGD/MalariaF/MGPG1255
**Keyword(s):** PGD Patient Group Direction Prophylaxis, Atovaquone, Proguanil, Mefloquine, Doxycycline

**Policy Statement:** It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

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| Document: | Drafted: | April 2022 |
| | Completed: | May 2022 |
| | Approved: | June 2022 (published – July 2022) |
| | Amended and reauthorised: | |

## Organisational Authorisations

**This PGD is not legally valid until it has had the relevant organisational authorisation.**

**PGD Developed/Reviewed by;**

| | |
|---|---|
| **Medical practitioner** | **Name:** Dr Maggie Watts<br>**Health Board:** NHSWI<br>**Title:** Director of Public Health<br>**Contact email:** maggie.watts@nhs.scot<br>**Signature:** .....<br>**Date:** 15/06/2022 |
| **Senior representative of the professional group who will provide care under the direction** | **Name:** Anne Marshall<br>**Health Board:** NHSG<br>**Title:** Community Pharmacist<br>**Contact email:**anne.marshall5@nhs.scot<br>**Signature:** .....<br>**Date:** 21/06/2022 |
| **Lead author** | **Name:** Frances Adamson<br>**Health Board:** NHSG<br>**Title :** Medicines Management Specialist Nurse<br>**Contact email:** frances.adamson@nhs.scot<br>**Signature:** ...<br>**Date:** 24/05/2022 |
| **Pharmacist** | **Name:** Liam Callaghan<br>**Health Board:** NHSWI<br>**Title :** Chief Pharmacist<br>**Contact email:** liam.callaghan@nhs.scot<br>**Signature:** .....<br>**Date:** 29/06/2022 |

**Approved for use within NoS Boards by;**

| North of Scotland (NoS) PGD Group Chair | Signature | Date Signed |
|---|---|---|
| Lesley Coyle |  | 15/06/2022 |

**Authorised and executively signed for use within NoS Boards by;**

| NHS Grampian Chief Executive | Signature | Date Signed |
|---|---|---|
| Professor Caroline Hiscox |  | 01/07/2022 |

**Management and Monitoring of Patient Group Direction**

**PGD Consultative Group**

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

| Name: | Title: |
|---|---|
| Frances Adamson | **Lead Author:** Medicines Management Specialist Nurse NHSG |
| Liam Callaghan | **Pharmacist:** Chief Pharmacist NHSWI |
| Dr Maggie Watts | **Medical Practitioner:** Director of Public Health NHSWI |
| Anne Marshall | **Senior Representative:** Community Pharmacist NHSG |
| Jackie Agnew | Head of Community Pharmacy Services NHSH |
| Alistair Brand | Consultant in Public Health Pharmacy NHST |
| Russell Mackay | Clinical Pharmacist NHSO |
| Mary McFarlane | Principal Pharmacist NHSS |

# Patient Group Direction For The Supply Of Medicines Included In The Malaria Prophylaxis PGD Formulary By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

## Clinical indication to which this PGD applies

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| **Definition of situation/ Condition** | This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to supply medicines as included in the Malaria Prophylaxis PGD Formulary to individuals requiring malaria prophylaxis for travel purposes.<br><br>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), the individual Summary of Product Characteristics (SmPC) and the Advisory Committee Malaria Prevention (ACMP) Guidelines for malaria prevention in travellers from the UK 2021. |
| **Inclusion criteria** | Travellers who are at moderate to high risk of exposure going to malaria endemic areas of the world where there is malaria.<br><br>**Note:** The ACMP Guidelines have a template for risk assessment and summary of advice given which can be used in conjunction with this PGD.<br><br>Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy. |
| **Exclusion criteria** | • Pregnancy<br>• Breastfeeding<br>• Where there is no valid consent.<br><br>**Note:** Age and other exclusions are specific to the medicines listed in the Malaria Prophylaxis PGD Formulary and each individual medicine monograph exclusion criteria should be considered in conjunction with the universal exclusions listed above. |
| **Precautions and special warnings** | • If there is any concern about the appropriate use of the medicine in the specific indications given within the PGD then medical advice should be sought.<br>• Precautions where listed in the individual monographs should be taken into account.<br>• The medicine Patient Information Leaflet (PIL) should be consulted to ensure that the individual has not experienced a previous hypersensitivity reaction to the medicine(s) or any of its excipients. |

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| **Action if excluded from treatment** | Medical advice must be sought – refer to relevant medical practitioner.<br><br>Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records. |
| **Action if treatment is declined** | The individual should be advised of the risks and consequences of not receiving treatment and the following must be discussed:<br><br>• Inform the individual that personal protection against being bitten is very important, whether taking medicinal prophylaxis or not.<br>• Wear long-sleeved clothing and long trousers if out at night.<br>• Use insect repellent on exposed skin and under thin clothing.<br>• Insecticide sprays, mosquito coils and heating insecticide impregnate tablets all reduce the risk of bites.<br>• Where possible sleep in screened rooms and use a mosquito net, preferably one impregnated with insecticide (permethrin).<br>• Use DEET together with sunscreen. **Note:** Inform individual that DEET can reduce the SPF factor of sunscreen.<br>• Diethyltoluamide (DEET) 20 - 50% in lotions, sprays, or roll-on formulations is safe and effective when applied to the skin of adults and children over 2 months of age.<br>• The duration of protection varies according to the concentration of DEET and is longest for DEET 50%.<br><br>Document that the supply was declined, the reason and advice given in appropriate clinical records. |

## Description of treatment available under the PGD

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| **Name form and strength of medicine** | See individual medicine monographs. |
| **Legal status** | The medicines included in this PGD are Prescription-only Medicines (POM) or Pharmacy (P).<br><br>**Note:** Atovaquone/Proguanil 250/100mg is marketed over the counter as Maloff® protect and is a Pharmacy (P) licensed product for adults aged 18 years and over. |

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| | In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. |
| **Dosage/Maximum total dose** | See individual medicine monographs. |
| **Frequency of dose/Duration of treatment** | See individual medicine monographs. |
| **Maximum or minimum treatment period** | See individual medicine monographs. |
| **Route/Method of administration** | Oral, for additional information see individual medicine monographs. |
| **Quantity to be supplied** | See individual medicine monographs. |
| **Storage requirements** | See individual medicine monographs. |
| **Follow-up (if applicable)** | N/A |
| **Advice (Verbal)** | Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions.<br><br>If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/ NHS24.<br><br>Should individuals experience serious adverse or persistent effects whilst abroad they should be advised to attend their nearest emergency medicine facility. |
| **Advice (Written)** | The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. |

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| **Identifying and managing possible adverse reactions** | See individual medicine monographs.<br><br>**This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.**<br><br>**BNF/BNFC**:<br>BNF British National Formulary - NICE<br>BNF for Children British National Formulary - NICE<br><br>**SmPC/PIL/Risk Minimisation Material:**<br>Home - electronic medicines compendium (emc)<br>MHRA Products \| Home<br>RMM Directory - (emc)<br><br>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.<br><br>Report any severe reactions using the Yellow Card System.<br>Yellow Card Scheme - MHRA |
| **Facilities and supplies required** | The following are to be available at sites where the medicine is to be supplied:<br>• Appropriate storage facilities<br>• An acceptable level of privacy to respect individual's right to confidentiality and safety<br>• Access to a working telephone<br>• Access to medical support (this may be via the telephone)<br>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel<br>• A copy of this current PGD in print or electronically. |

## Characteristics of staff authorised to supply medicine(s) under PGD

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| **Professional qualifications** | Those registered healthcare professionals that are listed and approved in legislation as able to operate under Patient Group Directions, as identified and included in individual Board travel health delivery plans. |
| **Specialist competencies** | **Approved by the organisation as:**<br>• Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent<br>• Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual |

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| | • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD<br>• Competent to undertake supply of the medicine<br>• Competent to work under this PGD. |
| **Ongoing training and competency** | **All professionals working under this PGD must:**<br>• Have undertaken NoS PGD module training on TURAS Learn<br>• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct<br>• Have knowledge and familiarity of the following;<br>  ○ SmPC for the medicine(s) to be supplied in accordance with this PGD. |
| **Responsibilities of professional manager(s)** | **Professional manager(s) will be responsible for;**<br><br>Ensuring that the current PGD is available to all staff providing care under this direction.<br><br>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.<br><br>Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction. |

## Documentation

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| **Authorisation of supply** | Qualified health professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to supply the medicine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:<br><br>Nurses, midwives and health visitors can be authorised by their line manager.<br><br>Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. |

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| | The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists.<br><br>All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1).<br><br>A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board. |
| **Record of supply** | An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:<br>• Date and time of supply<br>• Individuals name and CHI<br>• Exclusion criteria, record why the medicine was not supplied (if applicable)<br>• Record that valid consent to treatment under this PGD was obtained<br>• The name, dose, form, route of the medicine supplied<br>• Advice given, including advice given if excluded or declined treatment under this PGD<br>• Signature and name in capital letters of the healthcare professional who supplied the medicine<br>• Record of any adverse effects (advise individuals GP/relevant medical practitioner).<br><br>Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:<br>• Individual service specific systems. |
| **Audit** | All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD. |

**References**

Electronic Medicines Compendium http://www.medicines.org.uk Accessed 26/04/2022.

| Medicine | Date of Review |
|---|---|
| Atovaquone/proguanil 62.6/25mg (Malarone® paediatric) | 21/12/20 |
| Atovaquone/proguanil 250/100mg (Malarone®) | 21/12/20 |
| Doxycycline 100mg Capsules | 22/01/21 |
| Mefloquine (Lariam®) 250mg Tablets | 02/11/20 |

British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/accessed 26/04/2022.

Advisory Committee on Malaria Prevention (ACMP) for malaria prevention in travellers from the UK 2021 Malaria prevention guidelines for travellers from the UK - Publications - GOV.UK

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**Appendix 1**

## Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

**I:** _____ (Insert name)

**Working within:** _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

## Patient Group Direction For The Supply Of Medicines Included In The Malaria Prophylaxis PGD Formulary By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

**Signed:** _____

**Print Name:** _____

**Date:** _____

**Profession:** _____

**Professional Registration number/PIN** _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

**Appendix 2**

## Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

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| **The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated. |
| **The Senior Nurse/Professional** who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons. |
| **The Healthcare Professional** that is approved to supply the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct. |
| **Patient Group Direction For The Supply Of Medicines Included In The Malaria Prophylaxis PGD Formulary By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles** |
| **Local clinical area(s) where the listed healthcare professionals will operate under this PGD:** |

| Name of Healthcare Professional | Signature | Date | Name of Manager | Signature | Date |
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| Patient Group Direction For The Supply Of Medicines Included In The Malaria Prophylaxis PGD Formulary By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles | | | | | |
|---|---|---|---|---|---|
| **Name of Healthcare Professional** | **Signature** | **Date** | **Name of Manager** | **Signature** | **Date** |
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NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

**Appendix 3**

# Malaria Prophylaxis PGD Formulary

**Medicine** **Page no**

Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply) ..... 12

Doxycycline 100mg Capsules (Supply) ..... 16

Mefloquine 250mg Tablets (Lariam®) (Supply) ..... 19

| Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply) | |
|---|---|
| **Legal Status** | POM or P<br><br>**Note:** Atovaquone/Proguanil 250/100mg is marketed over the counter as Maloff® protect and is a Pharmacy (P) licensed product for adults aged 18 years and over. |
| **Indication** | Malaria prophylaxis for travel purposes. |
| **Inclusion Criteria** | Travellers who are at moderate to high risk of exposure going to malaria endemic areas of the world where there is atovaquone/proguanil sensitive *P. falciparum* malaria. |
| **Exclusion Criteria** | As per main PGD exclusion criteria and additionally:<br><br>• Individuals who have a known hypersensitivity to atovaquone or proguanil hydrochloride or any component of the formulation. See SmPC for details.<br>• Individuals who have severe renal impairment (creatinine clearance <30mL/minute).<br>• Individuals who are under 5kg in weight.<br>• Individuals taking the following medications:<br>  ○ Rifampicin<br>  ○ Rifabutin<br>  ○ Metoclopramide<br>  ○ Tetracycline<br>  ○ Efavirenz or boosted protease-inhibitors<br>  ○ Etoposide<br>• Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine.<br><br>**You must refer to latest edition of the BNF Appendix 1 to check all medicines the individual takes to check for an interaction.** |
| **Precautions and Special Warnings** | Caution is advised when initiating or withdrawing malaria prophylaxis in individuals on continuous treatment with warfarin and other coumarin based anticoagulants as the dose of the oral anticoagulant may need to be adjusted during atovaquone/proguanil treatment or after its withdrawal, based on INR results (see ACMP Guidelines section Advice for travellers needing malaria chemoprophylaxis who are taking warfarin). |

<table>
<tr><th colspan="2">Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply)</th></tr>
<tr><td></td><td>Persons taking atovaquone/proguanil for prophylaxis of malaria should take a repeat dose if they vomit within 1 hour of dosing. In the event of diarrhoea, normal dosing should be continued.<br><br>Proguanil is primarily metabolised by CYP2C19. However, potential pharmacokinetic interactions with other substrates, inhibitors (e.g. moclobemide, fluvoxamine) or inducers (e.g. artemisinin, carbamazepine) of CYP2C19 are unknown, caution is advised for any individuals currently prescribed these medicines.</td></tr>
<tr><td>Dose/Maximum total dose</td><td>Adult and children weighing 40kg or over:<br>Atovaquone/proguanil 250mg/100mg one tablet daily to be started 1–2 days before entering endemic area and continued for 1 week after leaving.<br><br>Children<br>The dosage for the prophylaxis of malaria in children weighing 5 to less than 40kg is based on body weight. See Table 1 below for dosing.<br><br>Note: The supply of atovaquone/proguanil 62.5mg/25mg tablets to children weighing less than 11kg is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. However, the use of the medicine in this way is in-line with recommendations in the ACMP Guidelines under Special Categories. The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label.<br><br>Table 1 – Prophylactic dosage in children weighing 5kg to less than 40 kg using paediatric Atovaquone/proguanil 62.5mg/25mg tablets.<br><br>
<table>
<tr><th>Body Weight Range in kg</th><th>Atovaquone (mg) dose</th><th>Proguanil (mg) dose</th><th>Dosage Regime</th></tr>
<tr><td>5 - 7.9kg</td><td>31.25mg</td><td>12.5mg</td><td>½ tablet once daily</td></tr>
<tr><td>8 – 9.9kg</td><td>46.8mg</td><td>18.75mg</td><td>¾ tablet once daily</td></tr>
<tr><td>10 – 19kg</td><td>62.5mg</td><td>25mg</td><td>1 tablet once daily</td></tr>
<tr><td>20 – 29kg</td><td>125mg</td><td>50mg</td><td>2 tablets once daily</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th colspan="2">Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply)</th></tr>
<tr><td></td><td>
<table>
<tr><th>Body Weight Range in kg</th><th>Atovaquone (mg) dose</th><th>Proguanil (mg) dose</th><th>Dosage Regime</th></tr>
<tr><td>30 – 39kg</td><td>187.5mg</td><td>75mg</td><td>3 tablets once daily</td></tr>
</table>
Reference BNFC atovaquone with proguanil hydrochloride.
</td></tr>
<tr><td>Frequency of dose/Duration of treatment</td><td>Prophylaxis of malaria with atovaquone/proguanil should begin 1-2 days before travel to malarial areas.<br><br>Thereafter to be taken daily during travel in the malarial areas and for 7 days after the traveller leaves the malarial area.</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>Variable, 1 to 2 days before entering a malarious area, continuing throughout the time in the area and for 7 days after leaving the area.</td></tr>
<tr><td>Route/Method of Administration</td><td>The tablets should be taken orally with food or a milky drink (to ensure maximum absorption) at the same time each day.</td></tr>
<tr><td>Quantity to be supplied</td><td>Quantity to be supplied should be duration of period in malarial area, plus 8-9 doses (1-2 days before and 7 days after).</td></tr>
<tr><td>Potential Adverse Reactions</td><td>Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects.<br><br>The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product’s known adverse effects:<br><br>The most common adverse reactions to atovaquone/proguanil prophylaxis are:<br><br>
Abdominal Pain — Dizziness — Diarrhoea<br>
Insomnia — Anaemia — Headache<br>
Abnormal Dreams — Vertigo — Depression<br>
Allergic reactions — Anorexia — Rash<br>
Fever — Pruritus — Cough<br>
Neutropenia — Hyponatraemia — Elevated liver enzymes</td></tr>
</table>

| Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply) | |
|---|---|
| **Advice** | Advice should be given on what to expect and what to do for major and minor reactions. If Individuals are concerned about any unwanted effects they need to seek medical advice as soon as possible and before taking their next tablet.<br><br>In the event of vomiting advise that a repeat dose should be taken if they vomit within 1 hour of dosing. In the event of diarrhoea, normal dosing should be continued.<br><br>Individuals should be reminded of the need to take the antimalarial on a regular basis and given advice on missed doses.<br><br>The individual should be made aware that any illness that occurs within 1 year and especially within 3 months of return might be malaria even if all recommended precautions against malaria were taken. Travellers should be warned of this and told that if they develop any illness particularly within 3 months of their return they should go immediately to a doctor and specifically mention their exposure to malaria.<br><br>The individual should be advised that personal protection against being bitten is very important, see page 2 of this PGD. |
| **Follow up (If applicable)** | Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing. |
| **Storage** | Store in the original package in order to protect from moisture.<br><br>PVC-Aluminium foil blister only: Do not store above 25°C. |

| Doxycycline 100mg Capsules (Supply) | |
|---|---|
| **Legal Status** | POM |
| **Indication** | Malaria prophylaxis for travel purposes in adults and children over the age of 12 years. |
| **Inclusion Criteria** | Malaria prophylaxis with doxycycline is particularly recommended for travellers to malarious areas in which multiple resistant *Plasmodium falciparum* strains occur. |
| **Exclusion Criteria** | As per main PGD exclusion criteria and additionally:<br><br>• Children under 12 years of age<br>• Individuals who have a known hypersensitivity to doxycycline, any of the capsule ingredients or to any of the tetracyclines<br>• Known severe hepatic impairment<br>• Known severe renal impairment<br>• Presence of concomitant conjunctivitis and/or joint pain/swelling<br>• Acute porphyria<br>• Individuals with Myasthenia gravis<br>• Individuals with Systemic Lupus Erythematosus (SLE)<br>• Individuals with oesophagitis and oesophageal ulcerations<br>• Treatment with acitretin, alitretinoin, isotretinoin or tretinoin - increased risk of benign intracranial hypertension when given with doxycycline<br>• Individuals currently taking methoxyflurane<br>• Warfarin - doxycycline increases the risk of bleeding events when given with warfarin and so INR should be monitored<br>• Individuals with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline.<br><br>**You must refer to latest edition of the BNF Appendix 1 to check all medicines the individual takes to check for an interaction.** |
| **Precautions and Special Warnings** | Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including doxycycline. Individuals likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema. |

| Doxycycline 100mg Capsules (Supply) | |
|---|---|
| | Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving doxycycline in conjunction with penicillin.<br><br>Some individuals with spirochete infections may experience a Jarisch-Herxheimer reaction shortly after doxycycline treatment is started. Individuals should be reassured that this is a usually self-limiting consequence of antibiotic treatment of spirochete infections.<br><br>Use doxycycline with caution in individuals with alcohol dependence. |
| **Dose/Maximum total dose** | 100mg daily in adults and children over 12 years (total dose depends on travel time in malarial areas). |
| **Frequency of dose/Duration of treatment** | Prophylaxis of malaria with doxycycline should begin 1-2 days before travel to malarial areas.<br><br>Thereafter to be taken daily during travel in the malarial areas and for 4 weeks after the traveller leaves the malarial area. |
| **Maximum or minimum treatment period** | Variable, 1 to 2 days before entering a malarious area, continuing throughout the time in the area and for 4 weeks after leaving the area. |
| **Route/Method of Administration** | Capsules to be taken orally.<br><br>The capsules should be taken with food or a glass of water/milk at the same time each day. |
| **Quantity to be supplied** | Quantity to be supplied should be duration of period in malarial area, plus 30 doses (1-2 days before and 4 weeks after). |
| **Potential Adverse Reactions** | The following side effects are common with doxycycline (but may not reflect all reported side effects):<br>• Hypersensitivity reactions<br>• Headache<br>• Nausea<br>• Vomiting<br>• Hypotension<br>• Pericarditis<br>• Tachycardia<br>• Dyspnoea |

| Doxycycline 100mg Capsules (Supply) | |
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| | • Peripheral oedema<br>• Rashes including maculopapular and erythematous rashes, exfoliative dermatitis, erythema<br>• Photosensitivity skin reactions. |
| **Advice** | Advice should be given on what to expect and what to do for major and minor reactions. If individuals are concerned about any unwanted effects they need to seek medical advice as soon as possible and before taking their next tablet.<br><br>Avoid direct skin contact to UV rays. Avoid excessive sun exposure and the use of sun beds to be avoided whilst taking doxycycline.<br><br>The absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these cations; oral zinc, iron salts or bismuth preparations. Dosages should be maximally separated.<br><br>Individuals should be reminded of the need to take the antimalarial on a regular basis and given advice on missed doses.<br><br>The individual should be made aware that any illness that occurs within 1 year and especially within 3 months of return might be malaria even if all recommended precautions against malaria were taken. Travellers should be warned of this and told that if they develop any illness particularly within 3 months of their return they should go immediately to a doctor and specifically mention their exposure to malaria.<br><br>The Individual should be advised that personal protection against being bitten is very important, see page 2. |
| **Follow up (If applicable)** | Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing. |
| **Storage** | Do not store above 25°C. |

| Mefloquine 250mg Tablets (Lariam®) (Supply) | |
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| **Legal Status** | POM |
| **Indication** | Malaria prophylaxis for travel purposes. |
| **Inclusion Criteria** | Individuals aged over 3 months or weighing more than 5kg who are at moderate to high risk of exposure going to malaria endemic areas of the world where there is mefloquine sensitive *Plasmodium falciparum* malaria. |
| **Exclusion Criteria** | As per main PGD exclusion criteria and additionally:<br><br>• Infants less than 3 months old or weighing less than 5kg<br>• Severe impairment of liver function<br>• Renal impairment or any insufficiency<br>• Active depression, a history of depression, generalised anxiety disorder, psychosis, suicide attempts, suicidal ideations and self-endangering behaviour, schizophrenia or other psychiatric disorders<br>• History of epilepsy or convulsions of any origin<br>• Known hypersensitivity to mefloquine or related compounds, e.g. quinine or quinidine (see SmPC)<br>• Individuals taking halofantrine<br>• Individuals with cardiac conduction disorders<br>• Individuals who are pilots employed by the UK Civil Aviation Authority<br>• History of Blackwater Fever<br>• Individuals taking other medicines known to alter cardiac conduction (e.g. anti-arrhythmic or beta-adrenergic blocking agents, calcium channel blockers, antihistamines or $H_1$-blocking agents, tricyclic antidepressants and phenothiazines)<br>• Individuals taking bupropion<br>• Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.<br><br>**You must refer to latest edition of the BNF Appendix 1 to check all medicines the individual takes to check for an interaction.** |
| **Precautions and Special Warnings** | Mefloquine may induce psychiatric symptoms such as anxiety disorders, paranoia, depression, hallucinations and psychosis. Psychiatric symptoms such as insomnia, abnormal dreams/nightmares, acute anxiety, depression, restlessness or confusion have to be regarded as prodromal for a more serious event. |

| Mefloquine 250mg Tablets (Lariam®) (Supply) | |
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| | Cases of suicide, suicidal thoughts and self-endangering behaviour such as attempted suicide have been reported.<br><br>Individuals on malaria chemoprophylaxis with mefloquine should be informed that if these reactions or changes to their mental state occur during mefloquine use, to stop taking mefloquine and seek medical advice immediately so that mefloquine can be replaced by alternative malaria prevention medication.<br><br>Adverse reactions may also occur after discontinuation of the drug. In a small number of individuals it has been reported that neuropsychiatric reactions (e.g. depression, dizziness or vertigo and loss of balance) may persist for months or longer, even after discontinuation of mefloquine.<br><br>Antimalarial prophylaxis may potentiate the effect of warfarin and other coumarin based anticoagulants which may lead to an increase in the risk of haemorrhage. Caution is therefore advised when initiating or withdrawing malaria prophylaxis or treatment in individuals on continuous treatment with oral coumarin based anticoagulants.<br><br>When mefloquine is taken concurrently with oral live typhoid vaccines, attenuation of immunisation cannot be excluded. Vaccinations with oral attenuated live bacteria should therefore be completed at least 3 days before the first dose of mefloquine.<br><br>Caution should be exercised in individuals taking Inhibitors and Inducers of CYP3A4 as these may modify the pharmacokinetics/metabolism of mefloquine. |
| **Dose/Maximum total dose** | Prophylaxis dosage guidelines from SmPC for Mefloquine 250mg tablets (Lariam®).<br><br>Adults and children of more than 45kg bodyweight 1 tablet per week.<br><br>The doses in Table 2 below differ from the doses specified in the Lariam® SmPC, however, the use of the medicine in this way is in-line with recommendations in the ACMP Guidelines under Special Categories. |

<table>
<tr><th colspan="2">Mefloquine 250mg Tablets (Lariam®) (Supply)</th></tr>
<tr><td></td><td>Table 2 - Prophylactic dosage in children weighing 5kg to less than 45kg using mefloquine 250mg tablets (Lariam®)<br><br>Children and adults weighing less than 45kg<br><br>5 – 9.9kg ¼ tablet (62.5mg)<br>10 – 15.9kg ¼ tablet (62.5mg)<br>16 – 24kg ½ tablet (125mg)<br>25 – 44.9kg ¾ tablet (187.5mg)</td></tr>
<tr><td>Frequency of dose/Duration of treatment</td><td>Prophylaxis of malaria with mefloquine should begin 10 days before departure (i.e. first intake 10 days before departure and 2nd intake 3 days before departure).<br><br>Subsequent doses should be taken once a week (on a fixed day). Treatment should be continued for 4 weeks after leaving a malarious area (minimum treatment period 6 weeks).<br><br>The maximum recommended duration of administration of mefloquine is 12 months.</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>See Frequency of dose/Duration of treatment section above.</td></tr>
<tr><td>Route/Method of Administration</td><td>The tablets should be taken orally preferably after food and with plenty liquid (to ensure maximum absorption) on the same day each week.</td></tr>
<tr><td>Quantity to be supplied</td><td>Minimum supply of one box of 8 Lariam® 250mg tablets.<br>Maximum supply of three boxes of 8 Lariam® 250mg tablets.</td></tr>
<tr><td>Potential Adverse Reactions</td><td>The most common adverse reactions to mefloquine prophylaxis are;<br><br>Nausea Dizziness Vomiting<br>Insomnia Vivid Dreams Headache<br>Visual Impairment Vertigo Depression<br>Anxiety Pruritus Diarrhoea<br><br>Individuals should be advised to obtain medical advice before the next weekly dose of mefloquine, if any concerning or neuropsychiatric symptoms develop. Discontinuation of mefloquine should be considered, particularly if neuropsychiatric reactions occur. The need for alternative antimalarial therapy or prophylaxis can then be evaluated.</td></tr>
</table>

| Mefloquine 250mg Tablets (Lariam®) (Supply) | |
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| | Adverse reactions may also occur after discontinuation of mefloquine. In a small number of individuals it has been reported that neuropsychiatric reactions (e.g. depression, dizziness or vertigo and loss of balance) may persist for months or longer, even after discontinuation. |
| **Advice** | Advice should be given on what to expect and what to do for major and minor reactions. If individuals are concerned about any unwanted effects they need to seek medical advice as soon as possible and before taking their next tablet.<br><br>Individuals should be advised to consult a doctor, if signs of arrhythmia or palpitations occur during chemoprophylaxis with mefloquine. These symptoms might, in rare cases, precede severe cardiologic side effects.<br><br>Individuals should be advised to obtain medical advice before the next weekly dose of mefloquine, if any concerning or neuropsychiatric symptoms develop.<br><br>**Note:** A Patient alert card should be carried and is available from https://www.medicines.org.uk/emc/rmm-directory under Lariam®.<br><br>Pneumonitis of possible allergic etiology has been reported in individuals receiving mefloquine. Individuals who develop signs of dyspnoea, dry cough or fever, etc while receiving mefloquine should be advised to contact a doctor to undergo medical evaluation.<br><br>Women of childbearing potential travelling to malarious areas who are receiving mefloquine for prophylaxis of malaria should take reliable contraceptive precautions for the entire duration of therapy and for three months after the last dose of mefloquine. In case of unplanned pregnancy, malaria chemoprophylaxis with Lariam® is not considered as an indication for pregnancy termination. For use of mefloquine during pregnancy, current national and international guidelines should be consulted.<br><br>Individuals should be reminded of the need to take the antimalarial on a regular basis and given advice on missed doses. |

| Mefloquine 250mg Tablets (Lariam®) (Supply) | |
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| | Caution should be exercised with regard to activities requiring alertness and fine motor coordination such as driving, piloting aircraft, operating machinery and deep sea diving, as dizziness, vertigo or a loss of balance, or other disorders of the central or peripheral nervous system and psychiatric disorders have been reported during and following the use of mefloquine. These effects may occur after therapy is discontinued. In a small number of individuals, it has been reported that dizziness or vertigo and loss of balance may persist for months or longer, even after discontinuation of mefloquine.<br><br>The individual should be made aware that any illness that occurs within 1 year and especially within 3 months of return might be malaria even if all recommended precautions against malaria were taken. Travellers should be warned of this and told that if they develop any illness particularly within 3 months of their return they should go immediately to a doctor and specifically mention their exposure to malaria.<br><br>The individual should be advised that personal protection against being bitten is very important, see page 2. |
| **Follow up (If applicable)** | Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing. |
| **Storage** | Do not store above 30°C, store in the original package in order to protect from moisture. |