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

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

Signature:		**Signature:**

NoS Identifier: NoS/PGD/MalariaF/1662	**Review Date:** June 2027 **Expiry Date:** June 2028	**Date Approved:** 25th of June 2025

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 2

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	Supersedes NoS/PGD/MalariaF/MGPG1255, Version 1	
Date of change	**Summary of Changes**	**Section heading**
December 2024	New PGD Template and update	
January 2025	Off label information moved to new section as per new template	Is the use out with the SmPC?
January 2025	Body weight range updated on table as per UKMEAG guidelines to Atovaquone/Proguanil monograph	Dose/Maximum total dose
January 2025	Note added about tablets being crushed to Atovaquone/Proguanil monograph	Route/Method of Administration
January 2025	Link to advice for Parents and carers on malaria prevention in children	Advice
January 2025	Advised to swallow tablets whole – Doxycycline monograph	Route/Method of Administration
April 2025	Additional information added around the use of DEET and higher SPF sunscreen	Action if treatment is declined
April 2025	Doxycycline monograph additional information added around minimum weight	Exclusion Criteria
April 2025	Mefloquine (Lariam) monograph additional information added about the breaking of tablets for children	Route/Method of Administration
April 2025	Mefloquine or atovaquone-proguanil Monographs addition information added about accuracy of medication when breaking of tablets	Dose/Maximum total dose
April 2025	Doxycycline monograph additional information added about storage	Storage
May 2025	ACMP updated as now known as UKMEAG.	Throughout
May 2025	Hyperlinks updated	Throughout
May 2025	Mosquito bite avoidance advice link added	Advice Written
May 2025	Methoxyflurane removed and ciclosporin added	Doxycycline Monograph

May 2025	Avoid the use of Ketoconazole as contraindicated and neuropathy added within adverse reactions. Storage temperature changed Statement added about providing an appropriate container for storage of half tablets	Mefloqine Monograph
May 2025	Removed extended HCP from list	Authorisation of supply
June 2025	Additional information regarding recommendations tailored to individual and risks/benefits	Definition of situation/condition
June 2025	Additional information or preventative measures added	Action if treatment is declined
June 2025	Additional information regarding advising GP	Advice (written)
June 2025	Reference to ACMP guidelines	Specialist Competencies
June 2025	Title dose table updated. Potential adverse reactions updated. Advice information re dizziness added.	Monograph – Atovaquone/ Proguanil
June 2025	Addition to exclusions re hepatotoxic drugs, carbamazepine and phenytoin. Addition of serious skin reactions to Precautions and Special Warnings. Additional information added to Advice section.	Monograph - Doxycycline
June 2025	Addition in Precautions and Special Warnings re epilepsy. Additional information in Potential Adverse Reactions. Additional advice re diving.	Monograph - Mefloquine

NoS Identifier: NoS/PGD/MalariaF/1662
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.

Document:	Drafted:	December 2024
	Completed:	May 2025
	Approved:	June 2025
	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 Jenny Wares **Health Board**:NHSH **Title:** Consultant in Public Health Medicine **Contact email:** jenny.wares@nhs.scot **Signature:** **Date:** 24/06/2025
Senior representative of the professional group who will provide care under the direction	**Name:** Bethany Carstairs **Health Board:** NHSG **Title:** Community Pharmacist **Contact email:** bethany.carstairs@nhs.scot. **Signature:** **Date:** 16/06/2025
Lead author	**Name:** Jodie Allan **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** Jodie.allan@nhs.scot **Signature:** **Date**: 05/06/2025
Pharmacist	**Name:** Gayle MacDonald **Health Board:** NHSH **Title : Vaccine Pharmacist** **Contact email:** gayle.macdonald@nhs.scot **Signature:** **Date:** 06/06/2525

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		24/06/2025

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		25/06/2025

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:
Jodie Allan	**Lead Author:** Medicines Management Specialist Nurse NHSG
Gayle MacDonald	**Pharmacist:** Vaccine Pharmacist NHST
Jenny Wares	**Medical Practitioner:** Consultant in Public Health Medicine
Bethany Carstairs	**Senior Representative:** Community Pharmacist NHSG

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

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. The recommendations for antimalarials should be appropriate for the destination and tailored to the individual, taking into account possible risks and benefits to the traveller. As part of an individual risk assessment it is essential that a full clinical history is obtained, detailing current medication, significant health problems and any known drug allergies. 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 UK Malaria Expert Advisory Group (UKMEAG) Guidelines for malaria prevention in travellers from the UK 2024.
Inclusion criteria	Travellers who are at moderate to high risk of exposure going to malaria endemic areas of the world where there is malaria. **Note:** The UKMEAG Guidelines have a template for risk assessment and summary of advice given which can be used in conjunction with this PGD (see appendix 2 of the document). 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 • Breastfeeding • Where there is no valid consent. **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. • Precautions where listed in the individual monographs should be taken into account. • 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.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. 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 and reinforced: • Inform the individual that personal protection against being bitten is very important, whether taking medicinal prophylaxis or not. This is also important to prevent other vector borne diseases. • Wear loose fitting, long-sleeved clothing, long trousers and socks when out of doors. Clothing may be sprayed or impregnated with an insecticide. • Use insect repellent on exposed skin and under thin clothing. • Insecticide sprays, mosquito coils and heating insecticide impregnate tablets all reduce the risk of bites. • Where possible sleep in screened rooms and use an insecticide-treated mosquito bed net. • Use DEET together with sunscreen. **Note:** Inform individual that DEET can reduce the SPF factor of sunscreen and advise to apply sunscreen first and use a higher SPF sunscreen. • 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. UKMEAG recommends a 50% DEET-based insect repellent as a first choice. • The duration of protection varies according to the amount of repellent applied to exposed skin and the concentration of DEET and is longest for DEET 50%. • Advice should also be given in relation to common myths pertaining to malaria prevention – see page 25/26 UKMEAG

	• Document that the supply was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

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). **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. 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.
Is the use out with the SmPC?	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 UKMEAG 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.
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. If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact the nearest appropriate medical facility. Should individuals experience serious adverse or persistent effects whilst abroad they should be advised to attend their nearest appropriate 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. PIL - Mosquito bite avoidance: advice for travellers - GOV.UK Safe and effective malaria prevention requires a sound knowledge of the medical history of the traveller. The General Medical Council states: "If you are not the patient's general practitioner and you accept a patient for treatment without a referral from the patient's practitioner, then you must: (a) explain to the patient the importance and benefits of keeping their general practitioner informed and (b) inform the patient's general practitioner unless the patient objects." In all scenarios where advice is given, a written record of the malaria prevention measures advised is given to the traveller so that they may pass it on to their GP.
Identifying and managing possible adverse reactions	See individual medicine monographs. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:**

	Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) **Stockley's Interaction Checker** If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Access to BNF/SmPC • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

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

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC) and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • 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 • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD and in accordance with current guidance such as UKMEAG guidelines. • Competent to undertake supply of the medicine • Competent to work under this PGD.

Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; o SmPC for the medicine(s) to be supplied in accordance with this PGD o UK Malaria Expert Advisory Group (UKMEAG) Guidelines for malaria prevention in travellers from the UK 2024.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintaining up to date records of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Nurses and pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles 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: Nurses can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1).

<table>
<tr><td></td><td>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.</td></tr>
<tr><td>Record of supply</td><td>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:
Date and time of supply
Individuals name and CHI
Exclusion criteria, record why the medicine was not supplied (if applicable)
Record that valid consent to treatment under this PGD was obtained
The name, dose, form, route of the medicine supplied
Advice given, including advice given if excluded or declined treatment under this PGD
Signature and name in capital letters of the healthcare professional who supplied the medicine
Record of any adverse effects (advise individuals GP/relevant medical practitioner).
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:
Individual service specific systems.</td></tr>
<tr><td>Audit</td><td>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.</td></tr>
<tr><td>References</td><td>Electronic Medicines Compendium
http://www.medicines.org.uk Accessed 28/01/25 & 30/01/25

<table><tr><th>Medicine</th><th>Date of Review</th></tr><tr><td>Atovaquone/proguanil 62.6/25mg (Malarone® paediatric)</td><td>28/01/25</td></tr><tr><td>Atovaquone/proguanil 250/100mg (Malarone®)</td><td>28/01/25</td></tr><tr><td>Doxycycline 100mg Capsules</td><td>30/01/25</td></tr><tr><td>Mefloquine (Lariam®) 250mg Tablets</td><td>30/01/25</td></tr></table></td></tr>
</table>

	British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online 28/01/25 & 30/01/25 UK Malaria Expert Advisory Group (UKMEAG) for malaria prevention in travellers from the UK 2024 Malaria prevention guidelines for travellers from the UK - Publications - GOV.UK

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

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, Version 2

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

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, Version 2
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

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, Version 2					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

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)	
Legal Status	POM or P **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: • Individuals who have a known hypersensitivity to atovaquone or proguanil hydrochloride or any component of the formulation. See SmPC for details. • Individuals who have severe renal impairment (creatinine clearance <30mL/minute). • Individuals who are under 5kg in weight. • Individuals taking the following medications: o Rifampicin o Rifabutin o Metoclopramide o Tetracycline o Efavirenz or boosted protease-inhibitors o Etoposide • Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine. **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 UKMEAG - 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.

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:
Atovaquone/proguanil 250mg/100mg one tablet daily to be started 1–2 days before entering endemic area and continued for 1 week after leaving.

Children
The dosage for the prophylaxis of malaria in children weighing 5kg to less than 40kg is based on body weight. See Table 1 below for dosing.

Table 1 – Prophylactic dosage in children weighing 5kg to less than 40 kg using paediatric Atovaquone/proguanil 62.5mg/25mg tablets.

<table>
<tr><th>Body Weight Range in kg</th><th>Atovaquone (mg) dose</th><th>Proguanil (mg) dose</th><th>Dosage Regime of Paediatric tablets (62.5/25mg)</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 – 19.9kg</td><td>62.5mg</td><td>25mg</td><td>1 tablet once daily</td></tr>
<tr><td>20 – 29.9kg</td><td>125mg</td><td>50mg</td><td>2 tablets once daily</td></tr>
<tr><td>30 – 39.9kg</td><td>187.5mg</td><td>75mg</td><td>3 tablets once daily</td></tr>
</table>

Reference BNFC atovaquone with proguanil hydrochloride and UKMEAG.

Note: Whilst it is preferable to avoid breaking and crushing tablets, and in the absence of syrup preparations, the</td></tr>
</table>

Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply)	
	appropriate dose of atovaquone/proguanil may be broken if dosing requires it and the drugs crushed if necessary and mixed with condensed milk, butter, oily spreads, full fat pasteurised yoghurt, jam, honey, or similar food to mask the bitter taste, to aid administration to young children. To minimise dose variation, when quarter tablets are required, each quarter from the same tablet should be taken on consecutive days; when half tablets are required, each half from the same tablet should be taken on consecutive days; and if the dose is three-quarters of a tablet, cutting 3 tablets into quarters in advance (total 12) and then giving 3 of the quarter tablets a day can provide 4 days' dosage and ensure that the correct dose is achieved as smoothly as practicable over that time period.
Frequency of dose/Duration of treatment	Prophylaxis of malaria with atovaquone/proguanil should begin 1-2 days before travel to malarial areas. Thereafter to be taken daily during travel in the malarial areas and for 7 days 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 7 days after leaving the area.
Route/Method of Administration	The tablets should be taken orally with food or a milky drink (to ensure maximum absorption) at the same time each day. Note: Paediatric tablets may be crushed and mixed with food or a milky drink just before administration
Quantity to be supplied	Quantity to be supplied should be duration of period in malarial area, plus 8-9 doses (1-2 days before and 7 days after).
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects:

Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply)	
	The most common adverse reactions to atovaquone/proguanil prophylaxis are: Abdominal Pain, Dizziness, Diarrhoea Insomnia, Anaemia, Headache Abnormal Dreams, Vertigo, Depression Allergic reactions, Anorexia, Rash Fever, Pruritus, Cough Neutropenia, Hyponatraemia, Elevated liver enzymes Nausea, Vomiting
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. Dizziness has been reported. Patients should be warned that if affected they should not drive, operate machinery or take part in activities where this may put themselves or others at risk. 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. Individuals should be reminded of the need to take the antimalarial on a regular basis and given advice on missed doses. 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. The individual should be advised that personal protection against being bitten is very important, see page 2 of this PGD. PIL for parent and carers - Malarone for prevention of malaria – Medicines For Children
Follow up (If applicable)	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.

Atovaquone/Proguanil 250/100mg Tablets and Atovaquone/Proguanil 62.5/25mg Paediatric Tablets (Supply)	
Storage	Store in the original package in order to protect from moisture. 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: • Children under 12 years of age • Body weight under 25 kg • Individuals who have a known hypersensitivity to doxycycline, any of the component ingredients or to any of the tetracyclines • Known severe hepatic impairment or those receiving potentially hepatotoxic drugs • Known severe renal impairment • Presence of concomitant conjunctivitis and/or joint pain/swelling • Acute porphyria • Individuals with Myasthenia gravis • Individuals with Systemic Lupus Erythematosus (SLE) • Individuals with oesophagitis and oesophageal ulcerations • Treatment with acitretin, alitretinoin, isotretinoin or tretinoin - increased risk of benign intracranial hypertension when given with doxycycline • Warfarin - doxycycline increases the risk of bleeding events when given with warfarin and so INR should be monitored • Individuals with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline. • Treatment with carbamazepine or phenytoin, as this accelerates the metabolism of doxycycline • Treatment with ciclosporin (risk of ciclosporin toxicity) **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

Doxycycline 100mg Capsules (Supply)	
	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. Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving doxycycline in conjunction with penicillin. Use doxycycline with caution in individuals with alcohol dependence. With respect to vaccines, doxycycline possibly reduces the efficacy of oral typhoid vaccine if given simultaneously. Preferably should not be started within 3 days after the last dose of vaccine.
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. 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. The capsules swallowed whole and should be taken with food or a glass of water/milk at the same time each day. The capsules should be swallowed with plenty of water in either the sitting or standing position - the individual should not lie down for at least one hour after ingestion, this reduces the risk of oesophageal irritation and ulceration.
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).

Doxycycline 100mg Capsules (Supply)	
Potential Adverse Reactions	The following side effects are common with doxycycline (but may not reflect all reported side effects): • Hypersensitivity reactions • Headache • Nausea • Vomiting • Hypotension • Pericarditis • Tachycardia • Dyspnoea • Peripheral oedema • Rashes including maculopapular and erythematous rashes, exfoliative dermatitis, erythema • Photosensitivity skin reactions. • Candida infections Benign intracranial hypertension has been associated with the use of tetracyclines including doxycycline. Benign intracranial hypertension is usually transient, however cases of permanent visual loss secondary to benign intracranial hypertension have been reported with tetracyclines including doxycycline. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted.
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. Avoid direct skin contact to UV rays. Avoid excessive sun exposure and the use of sun beds to be avoided whilst taking doxycycline. The individual should be advised to use a broad-spectrum sunscreen. 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. Individuals should be reminded of the need to take the antimalarial on a regular basis and given advice on missed doses.

Doxycycline 100mg Capsules (Supply)	
	If serious skin reactions occur, doxycycline should be discontinued immediately, and appropriate therapy should be instituted. If the traveller suffers vomiting or diarrhoea, the usual additional contraceptive precautions should be observed. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted due to risk of benign intercranial hypertension. 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. 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. Keep in the original package. Store in a dry place

Mefloquine 250mg Tablets (Lariam®) (Supply)	
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: • Infants less than 3 months old or weighing less than 5kg • Severe impairment of liver function • Renal impairment or any insufficiency • Active depression, a history of depression, generalised anxiety disorder, psychosis, suicide attempts, suicidal ideations and self-endangering behaviour, schizophrenia or other psychiatric disorders • History of epilepsy or convulsions of any origin • Known hypersensitivity to mefloquine or related compounds, e.g. quinine or quinidine (see SmPC) • Individuals taking halofantrine or any component in the formulation • Individuals with cardiac conduction disorders • Individuals who are pilots employed by the UK Civil Aviation Authority • History of Blackwater Fever • Individuals taking other medicines known to alter cardiac conduction (e.g. anti-arrhythmic or beta-adrenergic blocking agents, calcium channel blockers, antihistamines, ketocanazole or H_1-blocking agents, tricyclic antidepressants and phenothiazines) • Individuals taking bupropion • Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **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,

Mefloquine 250mg Tablets (Lariam®) (Supply)	
	restlessness or confusion have to be regarded as prodromal for a more serious event. Cases of suicide, suicidal thoughts and self-endangering behaviour such as attempted suicide have been reported. 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. 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. The risk of epilepsy and serious mental health disorders is higher in first-degree relatives of those in whom these conditions have been diagnosed so they should be considered as part of risk assessment. A condition in a first-degree relative may not contraindicate the use of an antimalarial but may influence the choice of drug. 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. 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. Caution should be exercised in individuals taking Inhibitors and Inducers of CYP3A4 as these may modify the pharmacokinetics/metabolism of mefloquine. In those who have suffered traumatic brain injury, the decision whether to advise mefloquine chemoprophylaxis should be made on an individual basis after a detailed risk assessment.

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	With respect to the military, the Ministry of Defence has prepared guidelines for malaria prevention specific to military personnel. Civilian practitioners asked to provide malaria prevention advice for members of the Armed Forces should liaise with the Defence Medical Services.
Dose/Maximum total dose	Prophylaxis dosage guidelines from SmPC for Mefloquine 250mg tablets (Lariam®). Adults and children of more than 45kg bodyweight 1 tablet per week. 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 UKMEAG Guidelines under Special Categories. **Table 2** - Prophylactic dosage in children weighing 5kg to less than 45kg using mefloquine 250mg tablets (Lariam®) Children and adults weighing less than 45kg 5 – 9.9kg ¼ tablet (62.5mg) 10 – 15.9kg ¼ tablet (62.5mg) 16 – 24kg ½ tablet (125mg) 25 – 44.9kg ¾ tablet (187.5mg) Reference BNFC mefloquine hydrochloride and UKMEAG. **Note:** Whilst it is preferable to avoid breaking and crushing tablets, and in the absence of syrup preparations, the appropriate dose of mefloquine may be broken if dosing requires it and the drugs crushed if necessary and mixed with condensed milk, butter, oily spreads, full fat pasteurised yoghurt, jam, honey, or similar food to mask the bitter taste, to aid administration to young children. To minimise dose variation, when quarter tablets are required, each quarter from the same tablet should be taken on consecutive days; when half tablets are required, each half from the same tablet should be taken on consecutive days; and if the dose is three-quarters of a tablet, cutting 3 tablets into quarters in advance (total 12) and then giving 3 of the quarter tablets a day can provide 4 days' dosage and

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	ensure that the correct dose is achieved as smoothly as practicable over that time period.
Frequency of dose/Duration of treatment	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). The reason this is pre-departure and not prior to arrival in a malarious area is due to the need to ensure mefloquine is well tolerated. Subsequent adult and paediatric 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). The maximum recommended duration of administration of mefloquine is 12 months.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of Administration	The tablets should be taken orally preferably after food and with plenty of liquid (to ensure maximum absorption) on the same day each week. Note: For children tablets can be divided by breaking along score lines.
Quantity to be supplied	Minimum supply of one box of 8 Lariam® 250mg tablets. Maximum supply of three boxes of 8 Lariam® 250mg tablets. Provide an appropriate container for storage of half tablets i.e. brown bottle
Potential Adverse Reactions	The most common adverse reactions to mefloquine prophylaxis are; Nausea, Dizziness, Vomiting Insomnia, Vivid Dreams, Headache Visual Impairment, Vertigo, Depression Anxiety, Pruritus, Diarrhoea Abdominal pain Individuals should be advised to obtain medical advice before the next weekly dose of mefloquine, if any

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	concerning, neuropathy 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. 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. Cases of polyneuropathy (based on neurological symptoms such as pain, burning, sensory disturbances or muscle weakness, alone or in combination) have been reported in patients receiving mefloquine. Mefloquine should be discontinued in patients experiencing symptoms of neuropathy, including pain, burning, tingling, numbness, and/or weakness in order to prevent the development of an irreversible condition.
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. 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. Individuals should be advised to obtain medical advice before the next weekly dose of mefloquine, if any concerning or neuropsychiatric symptoms develop. **Note:** A Patient alert card should be carried and is available from https://www.medicines.org.uk/emc/rmm-directory under Lariam®. 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.

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	Mefloquine should be discontinued in patients experiencing symptoms of neuropathy, including pain, burning, tingling, numbness, and/or weakness in order to prevent the development of an irreversible condition. 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. Individuals should be reminded of the need to take the antimalarial on a regular basis and given advice on missed doses. 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. With respect to diving, if the individual tolerates mefloquine prophylaxis there is no evidence that they cannot physically perform underwater diving. However, mefloquine does lower the seizure threshold and its side effects could potentially be confused with decompression or narcosis events. Some sub-aqua centres do not permit those taking mefloquine to dive and so mefloquine might therefore be better avoided for those undertaking diving holidays but there is no contraindication to its use in occasional divers who have taken and tolerated the drug before, or those able to start taking it early to ensure that no adverse events occur. 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

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	within 3 months of their return they should go immediately to a doctor and specifically mention their exposure to malaria. 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, store in the original package in order to protect from moisture.