Patient Group Direction For The Supply Of Mefloquine For The Prophylaxis Of Malaria By Nurses Working In Occupational Health And Pharmacists Working Within NHS Grampian

Lead Author: Medicines Management Specialist Nurse
Consultation Group: See relevant page in the PGD
Approver: NHSG Medicines Guidelines and Policies Group

Signature:

Identifier: NHSG/PGD_Mefloquine_MGPG952
Review Date: June 2020
Date Approved: June 2018
Expiry Date: June 2021

NHS Grampian 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 Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed
Version 7
**Revision History:**

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>2 yearly update.</td>
<td></td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Cardiac conduction disorders added.</td>
<td>Exclusion criteria</td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Individuals with epilepsy added.</td>
<td>Exclusion criteria</td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption added as tablets have 50mg of lactose monohydrate.</td>
<td>Exclusion criteria</td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Severe renal impairment added.</td>
<td>Exclusion criteria</td>
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<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Pilots added in accordance with ACMP Guidelines.</td>
<td>Exclusion criteria</td>
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<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Strength of DEET changed from 100% to 50% in-line with ACMP Guidelines.</td>
<td>Action if patient declines treatment</td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Further information added regarding when to initiating prophylaxis and ideal duration.</td>
<td>Duration of treatment</td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Information regarding patient alert card added.</td>
<td>Advice to patient (Verbal)</td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Information added regarding mefloquine use and diving.</td>
<td>Advice to patient (Verbal)</td>
</tr>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Statement regarding using Appendix 2 of the ACMP 2017 Guidelines in conjunction with the PGD added.</td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td>June 2018</td>
<td>July 2016</td>
<td>Statement added as per Fit For Travel NHS Site regarding doses to be given prior to travel to detect side effects.</td>
<td>Duration of treatment</td>
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</tbody>
</table>

**NHS Grampian Identifier:**

| NHSG/PGD_Mefloquine_MGPG952 |

**Replaces:**

| NHSG/PGD_Mefloquine_MGPG810, Version 6 |

**Keyword(s):**

| PGD Patient Group Direction Mefloquine, Malaria, Prophylaxis, Nurses, Pharmacists, Occupational Health |

**Policy Statement:** It is the responsibility of individual nurse or pharmacist 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 patient, 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 patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

**Document:**

<table>
<thead>
<tr>
<th>Drafted:</th>
<th>April 2018</th>
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<tbody>
<tr>
<td>Completed:</td>
<td>May 2018</td>
</tr>
<tr>
<td>Approved:</td>
<td>June 2018 (published – July 2018)</td>
</tr>
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</table>
Patient Group Direction For Use Within NHS Grampian

Organisational Authorisation

This PGD is not legally valid until it has had organisational authorisation

NHS Grampian

<table>
<thead>
<tr>
<th>Designation</th>
<th>Name</th>
<th>Signature</th>
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<tbody>
<tr>
<td>Medical Director</td>
<td>Nick Fluck</td>
<td></td>
<td>July 2018</td>
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<tr>
<td>Director of Pharmacy</td>
<td>David Pfleger</td>
<td></td>
<td>July 2018</td>
</tr>
<tr>
<td>Director of Nursing, Midwifery and</td>
<td>Caroline Hiscox</td>
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<td>July 2018</td>
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<tr>
<td>Allied Healthcare Professionals</td>
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</tbody>
</table>

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: 

Frances Adamson
Lesley Thomson
Dr Katherine Targett
Charles Michie
Rhiannon Sharp

Title: 

Lead Author: Medicines Management Specialist Nurse
Pharmacist: Lead Pharmacist Aberdeenshire H&SCP
Medical Practitioner: Consultant Occupational Physician
Community Pharmacist
Lead Travel Clinic Nurse

UNCONTROLLED WHEN PRINTED  Review Date: June 2018  Identifier: NHSG/PGD_Mefloquine_MGP952 - iii -
PGD for the supply of mefloquine by nurses in OHS and pharmacists – Version 7  Template Version 2.2
Clinical indication to which this PGD applies

| Definition of situation/condition | This Patient Group Direction (PGD) will authorise nurses working in Occupational Health and pharmacists working within NHS Grampian to supply mefloquine to individuals requiring malaria prophylaxis for travel purposes.

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC) and individual Summary of Product Characteristics (SmPC).

Refer to the Advisory Committee Malaria Prevention (ACMP) Guidelines for malaria prevention in travellers from the UK 2017 see link below.

Malaria prevention guidelines for travellers from the UK - Publications - GOV.UK. |
| 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.

**N.B.** The ACMP Guidelines (Appendix 2) have a template for risk assessment and summary of advice given which can be used in conjunction with this PGD. |
| Exclusion criteria | • 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 convulsions of any origin.

• Known hypersensitivity to mefloquine or related compounds, e.g. quinine. See SmPC for details.

• Individuals taking halofantrine.

• Individuals with cardiac conduction disorders. |
### 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.
- 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.

### Referral criteria

Individuals who fall into the categories detailed in the exclusion criteria.

### Action if excluded from treatment

Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner).

The reason why the patient was excluded under the PGD will be documented in the appropriate patient record.

### Action if patient declines treatment

The individual should be advised of the risks and consequences of not receiving treatment.

Inform the individual that personal protection against being bitten is very important. Mosquito nets impregnated with permethrin provide the most effective barrier protection against insects; mats and vaporised insecticides are also useful.

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. It can also be used during pregnancy and breastfeeding. The duration of protection varies according to the concentration of DEET and is longest for DEET 50%. Long sleeves and trousers worn after dusk also provide protection.
Record outcome in Patient Medication Record if appropriate, or relevant patient record.

### Consent

Prior to the supply of the drug, valid consent must be obtained. Consent must be in line with current NHSG consent policy.

### Description of treatment available under the PGD

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Mefloquine 250mg tablets (Lariam®).</th>
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</thead>
<tbody>
<tr>
<td><strong>Legal status</strong></td>
<td>Mefloquine is a Prescription-only Medicine (PoM). 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.</td>
</tr>
<tr>
<td><strong>Form/Strength</strong></td>
<td>Aluminium foil packs containing 8 white to off-white cylindrical biplanar cross-scored tablets for oral use. Each tablet contains 250mg of mefloquine.</td>
</tr>
<tr>
<td><strong>Route/Method of administration</strong></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>
</tbody>
</table>
| **Dosage/Total Dose** | Prophylaxis dosage guidelines from SmPC for Mefloquine 250mg tablets (Lariam®). Adults and children of more than 45 kg bodyweight 1 tablet per week. Children and adults weighing less than 45 kg  
5 – 19 kg ¼ tablet (62.5mg)  
20 – 30 kg ½ tablet (125mg)  
31 – 45 kg ¾ tablet (187.5mg) |
### 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).

However, three doses at weekly intervals prior to departure are advised if the drug has not been used before – this can detect in advance those likely to get side effects so that an alternative can be prescribed.

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).

The maximum recommended duration of administration of mefloquine is 12 months.

### Storage requirements

Do not store above 30°C, store in the original package in order to protect from moisture.

### Follow-up (if applicable)

Not applicable.

### Advice to patient (Verbal)

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.

Mefloquine can stay in the body for a long time after taking the last dose, therefore individuals should be advised that some adverse reactions may also occur and persist for months or longer after discontinuation of the drug.

Individuals should be advised to obtain medical advice before the next weekly dose of mefloquine, if any concerning or neuropsychiatric symptoms develop. **N.B.** A Patient alert card should be carried and is available from [https://www.medicines.org.uk/emc/rmm-directory](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.
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.

Individuals 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.

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.

**N.B.** Some sub-aqua centres do not permit those taking mefloquine to dive. 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.

These effects may occur after therapy is discontinued due to the long half-life of the drug. In a small number of individuals dizziness or vertigo and loss of balance have been reported to continue for months after discontinuation of the drug.

Inform the individual that personal protection against being bitten is very important. Mosquito nets impregnated with permethrin provide the most effective barrier protection against insects; mats and vaporised insecticides are also useful.

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. It can also be used during pregnancy and breastfeeding. The duration of protection varies according to the concentration of DEET and is longest for DEET 50%. Long sleeves and trousers worn after dusk also provide protection.
### Advice to patient (Written)

The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Copies of PIL and SmPCs for medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) or [http://www.mhra.gov.uk/spc-pil/index.htm](http://www.mhra.gov.uk/spc-pil/index.htm)

Additionally, the Patient Alert Card should be carried and is available from [https://www.medicines.org.uk/emc/rmm-directory](https://www.medicines.org.uk/emc/rmm-directory) under Lariam®.

### Concurrent Medications/Drug Interactions

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.

Concomitant administration of mefloquine and other related compounds (e.g. quinine, quinidine and chloroquine) may produce electrocardiographic abnormalities.

Concomitant administration of mefloquine and drugs known to lower the epileptogenic threshold (antidepressants such as tricyclic or selective serotonin reuptake inhibitors (SSRIs); antipsychotics; tramadol; chloroquine or some antibiotics) may increase the risk of convulsions.

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.

Inducers (rifampicin, carbamazepine, phenytoin, efavirenz) or inhibitors of the isoenzyme CYP3A4 may modify the pharmacokinetics/metabolism of mefloquine, leading to an increase or decrease in mefloquine plasma concentration.

Concomitant administration of drugs known to alter cardiac conduction (e.g. antiarrhythmic or beta-adrenergic blocking agents, calcium channel blockers, antihistamines or H1-blocking agents, tricyclic antidepressants and phenothiazines) might contribute to a prolongation of the QTc interval.
**Identifying and managing possible adverse reactions**

The most common adverse reactions to mefloquine prophylaxis are:

- Nausea
- Dizziness
- Vomiting
- Insomnia
- Vivid Dreams
- Headache
- Visual Impairment
- Vertigo
- Depression
- Anxiety
- Pruritus

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.

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 the drug.

This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.

**BNF/BNFC:**
[https://www.bnf.org](https://www.bnf.org)

**SmPC/PIL and risk minimisation materials:**
[https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)
[https://www.medicines.org.uk/emc/rmm-directory](https://www.medicines.org.uk/emc/rmm-directory)

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System. [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)

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**Facilities and supplies required**

The following should be available at sites where the medication is to be supplied:

- Appropriate storage facilities
- An acceptable level of privacy to respect patient’s right to confidentiality and safety
- Access to medical support (this may be via the telephone)
• Clean and tidy work areas, including access to hand washing facilities
• Copies of the current PGD for the medicine specified in the PGD.

**Characteristics of staff authorised to supply medicine under PGD**

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>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).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist competencies</td>
<td>Approved by the organisation as:</td>
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<tr>
<td></td>
<td>• Competent to assess the patient’s capacity to understand the nature and purpose of the supply in order for the patient to give or refuse consent</td>
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<td>• Having undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD</td>
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<td>• Aware of current treatment recommendations and be competent to discuss issues about the drug with the patient</td>
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<td></td>
<td>• The nurse or pharmacist providing the supply should be competent and experienced in counselling for travel.</td>
</tr>
</tbody>
</table>

**Ongoing training and competency**

All professionals working under this PGD must:

• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct
• Must be familiar with the SmPC for all medicines supplied in accordance with this PGD.

**Professional managers/Lead Nurses will be responsible for:**

Ensuring that the current PGD is available to 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.

Maintain up to date record of all staff authorised to supply drug specified in PGD.
### Documentation

| Authorisation of supply | Nurses working within NHS Grampian OHS can be authorised to supply the drug specified in this PGD by their Nurse Manager or Consultant. Pharmacists working within NHS Grampian can be authorised to supply the drug specified in this PGD by the Director of Pharmacy.  

All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). This should be held in the individual practitioners records, or as agreed locally.  

A Certificate of Authorisation (Appendix 2) signed by the authorising doctor/manager and staff working to the PGD, should be held as agreed locally. |
|---|---|
| Record of supply | An electronic or paper record for recording the screening of individuals and the subsequent supply of the drug 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  
- Patient Date of birth and CHI  
- Details of parent/guardian, or person with parental responsibility where applicable  
- Exclusion criteria, record why the drug was not supplied  
- Consent to the administration (if not obtained elsewhere)  
- Signature and name in capital letters of practitioner who supplied the drug  
- Record of any adverse effects (advise patient’s doctor).  

These records should be retained:  

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.  

**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above. |
| Audit | All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each H&SCP/practice/service will be responsible for auditing completion of drug forms and collation of data. |
Advisory Committee on Malaria Prevention (ACMP) for malaria prevention in travellers from the UK 2017 [Malaria prevention guidelines for travellers from the UK - Publications - GOV.UK](https://www.gov.uk/government/publications/malaria-prevention-guidelines-for-travellers-from-the-uk)  
Appendix 1

Health Care Professional Agreement to Supply Medicines Under Patient Group Direction

I: _____________________________ (Insert name)

Working within: ___________________________ e.g. H&SCP, Practice

Agree to supply medicines under the direction contained within the following Patient Group Direction

**Patient Group Direction For The Supply Of Mefloquine For The Prophylaxis Of Malaria By Nurses Working In Occupational Health And Pharmacists Working Within NHS Grampian**

I have completed the appropriate training to my professional standards enabling me to supply medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor out with the recommendations of the Patient Group Direction.

Signed: ___________________________

Print Name: ___________________________

Date: ___________________________

Professional Registration No: ___________________________
Appendix 2

Health Professionals Authorisation to Supply Medicines Under Patient Group Direction

The lead nurse/professional of each clinical area is responsible for maintaining records of their clinical area where this PGD is in use, and to whom it has been disseminated.

The manager who approves a healthcare professional to supply medicines under the patient group direction, 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 in conjunction with the Head of Profession.

The healthcare professional who is approved to supply medicines under the direction 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 code of professional practice and conduct.

Patient Group Direction For The Supply Of Mefloquine For The Prophylaxis Of Malaria By Nurses Working In Occupational Health And Pharmacists Working Within NHS Grampian

Local clinical area(s) where these healthcare professionals will operate under this PGD:

<table>
<thead>
<tr>
<th>Name of Healthcare Professional</th>
<th>Signature</th>
<th>Date</th>
<th>Name of Manager</th>
<th>Signature</th>
<th>Date</th>
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