Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB intranet to ensure that they are always working to the most up to date version

# Patient Group Direction

for the administration and supply of

**potassium iodate 85mg tablets**

by registered Healthcare Professionals

to

**Adults and Children**

**exposed to or at risk of exposure to radioactive iodine**

**in an emergency situation**

in Powys Teaching Health Board, community settings, GP practices or Powys Out of Hours Services.

**Version number: PGD 0190**

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Reference Number: PGD 0190
Valid from: 21/03/2022
Review date: 20/03/2024
Expiry date: 20/03/2025

## Change history

| Version number | Change details | Date |
|---|---|---|
| PGD0190 | Previously PGD0075 which was withdrawn.<br>Now as PGD0190 - issue UKHSA adopted. | 21/03/2022 |

**This PGD is based on the UKHSA protocol.**

## 1. Protocol Development

This protocol has been developed by the following on behalf of the UKHSA (UK Health Security Agency):

| Developed by: | Name |
|---|---|
| **Pharmacist** (Lead author) | Jacqueline Lamberty<br>Lead Pharmacist Medicines Governance,<br>Health Equity & Clinical Governance Directorate, UKHSA |
| **Doctor** | Nick Gent<br>Consultant in Health Protection,<br>Emergency Response Department, UKHSA |
| **Registered Nurse** | Kelly Stoker<br>Lead Immunisation Nurse Specialist,<br>Immunisation and Vaccine Preventable Diseases Division, UKHSA |

**Expert Panel**

| Name | Designation |
|---|---|
| Ruth Milton (Chair) | Senior Medical Adviser, Consultant in Public Health Emergency Response Department, UKHSA |
| Duncan Cox | Radiation Emergency Response Group Leader – Radiation, Chemical and Environmental Hazards Directorate, UKHSA |
| Jo Jenkins | Specialist Pharmacist (Patient Group Directions), Medicines Use and Safety Division, NHSEI |
| Michelle Jones | Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG |
| Axel Macdonald | Radiation Protection Adviser – Radiation, Chemical and Environmental Hazards Directorate, UKHSA |
| Prof Ray Powles | Head Haematooncology Cancer Centre London Chairman Conservative Health |

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| | Co-Chair European Blood and Marrow Transplant Nuclear Accident Committee<br>Co-Chair Global Emergency Nuclear Accident WBMT Society |
| Craig Prentice | Advanced Paramedic Practitioner, Surrey and Sussex Healthcare NHS Trust |

## PGD authorisation

| Name | Job title and organisation | Signature | Date |
|---|---|---|---|
| **Senior doctor**<br>**Dr Kate Wright** | Lead doctor for PTHB | DocuSigned by:<br>Kate Wright<br>1F267952823F473... | 4/1/2022 |
| **Chief Pharmacist**<br>**Jacqui Seaton** | Chief Pharmacist for PTHB | DocuSigned by:<br>Jacqui Seaton<br>71E8089DE3634C4... | 4/4/2022 |
| **Senior representative of professional group using the PGD**<br>**Claire Roche** | Executive Director of Nursing and Midwifery for PTHB | DocuSigned by:<br>claire roche<br>FC9C4C63FC374A7... | 4/1/2022 |
| **Clinical Governance Lead**<br>**Amanda Edwards** | Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement | DocuSigned by:<br>Amanda Edwards<br>74A4E51A42E9473... | 4/1/2022 |

**Appendix A** provides a staff accreditation sheet. Individual practitioners must be authorised by name to work under this PGD.

## PGD adoption by the provider

| Name | Job title and organisation | Signature | Date |
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## 2. Characteristics of Staff

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| **Qualifications and professional registration** | Practitioners must only work under this PGD where they are competent to do so.<br>Practitioners working under this Patient Group Direction (PGD) must also be a registered professional with one of the following bodies:<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)<br>(**NB:** This PGD is not relevant to privately provided community pharmacy services)<br>• chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)<br>• dental hygienists and dental therapists registered with the General Dental Council<br>• optometrists registered with the General Optical Council<br>The practitioners above must also fulfil the Additional requirements detailed below.<br><br>Check Appendix A – Staff Accredited to use Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD. |
| **Training and additional requirements** | Practitioners:<br>• Must have received training in the administration and supply of potassium iodate tablets, including method of administration in children and elderly with swallowing difficulties, and knowledge of its uses, contraindications and adverse effects<br>• must be familiar with the product(s) and alert to changes in the BNF and Summary of Product Characteristics<br>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it<br>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines (Evidence of ongoing PGD training to be submitted to Line Manager annually)<br>• must have completed Patient Group Directions training-available via ESR<br>• must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) |

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| | • must be competent in the recognition, management and reporting of adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills<br>• must have access to the PGD and associated online resources<br>• must have undertaken training appropriate to this PGD and should fulfil any additional requirements defined by local policy.<br><br>**THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**<br><br>**THE DECISION TO ADMINISTER ANY MEDICATION RESTS WITH THE INDIVIDUAL REGISTERED HEALTH PROFESSIONAL WHO MUST ABIDE BY THE PGD AND ANY ASSOCIATED ORGANISATIONAL POLICIES.** |
| **Continued training and competency** | • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, Life Support Skills, with evidence of appropriate Continued Professional Development (CPD).<br>• Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales UKHSA and/or NHSEI and other sources of medicines information.<br>• Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners must make a self-declaration of competency on PADR.<br>• Compliance with all mandatory NHS training.<br>**It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.** |

## 3. Clinical condition or situation to which this PGD applies

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| **Clinical condition or situation to which this PGD applies** | Known or suspected exposure to radioactive iodine or at risk of exposure, in an emergency situation. |

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| **Criteria for inclusion** | All age groups (adults, including pregnant or breast-feeding individuals, children, babies and neonates):<br>1. With known or suspected imminent exposure to radioactive iodine or at risk of exposure,<br>2. As a precautionary countermeasure as declared by the UKHSA.<br>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained prior to administration/supply.<br>Refer to PTHB Consent to Treatment and Examination Policy.<br>In case of any doubt, contact medical team or emergency services.<br>• Medical and drug history taken, no reason for exclusion<br><br>**Note:** Pregnant and breast-feeding individuals, neonates, infants and children are a priority for treatment. Prophylactic administration of potassium iodate to pregnant individuals is also effective in protecting the thyroid of the foetus.<br>Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought.<br><br>**It is the responsibility of the administering and supplying healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.** |
| **Criteria for exclusion** (Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside this PGDs remit and another form of authorisation will be required) | Individuals are excluded from this protocol if:<br>1. 24 hours or more has passed since the known or suspected exposure to radioactive iodine.<br>2. They have experienced anaphylaxis, severe allergy or sensitivity to any iodine containing medicines or any of the excipients in the tablets.<br>3. They have dermatitis herpetiformis or hypocomplementaemic vasculitis.<br>4. Conditions outside of the clinical situations criteria.<br>5. No valid consent or patient/representative refuses treatment.<br>Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if patient is excluded or "Action to be taken if patient declines treatment". |

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| | **NB**. Pregnancy and hyperthyroidism are **not** exclusion criteria. If pregnant individuals with active hyperthyroidism take potassium iodate there is a risk of foetal thyroid blockage. However, this contraindication has not been included because post-natal screening for hypothyroidism is undertaken in the UK. |
| **Cautions including any relevant action to be taken** | None |
| **Action to be taken if the patient is excluded** | Explain why they have been excluded, record the reason for exclusion and refer the individual to the supervising doctor.<br>If the supervising doctor decides the product can be administered, the doctor will need to provide a Patient Specific Direction. |
| **Action to be taken if the patient or carer declines treatment** | • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration/supply and recorded appropriately. The patient information leaflet should be available to inform consent. Where a person lacks capacity, in accordance with the Mental Capacity Act 2005, a decision to treat may be made in the patients' best interests.<br>• Advise the individual/parent/carer about the protective effects of the potassium iodate and the possible consequences of refusing treatment.<br>• Document advice given and the decision reached.<br>• In a GP practice setting, inform or refer to the GP as appropriate. |
| **Arrangements for referral for medical advice** | Refer to GP or a prescriber for clinical advice as necessary.<br><br>Document any advice given. |

## 4. Description of Treatment.

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| **Name, strength & formulation of drug** | Potassium iodate 85mg tablets equivalent to 50mg of iodine |
| **Legal category** | Pharmacy only (P) medicine |
| **Black Triangle▼** | No |
| **Off-label use** | Yes.<br>Although the Summary of Product Characteristics (SPC) states treatment should be initiated within one hour of exposure, |

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<tr><td></td><td>treatment should nevertheless be considered after this time period, as the likely benefits of treatment outweigh the likely risks of non-treatment. The timeframe will be decided according to local advice at the time of an incident.<br><br>However, commencing treatment later than 24 hours following exposure to radioactive iodine may do more harm than good by prolonging the biological half-life of radioactive iodine that has already accumulated in the thyroid.<br><br>Where a product is recommended off-label consider, as part of the consent process, informing the individual or their carer that the product is being offered in accordance with national guidance, but this is outside the product licence.</td></tr>
<tr><td>Route/method of administration</td><td>Oral.<br>For neonates (from birth to less than 1 month of age): crush the quarter tablet and dissolve it in a small quantity of milk or juice. Shake well to make sure the powder dissolves.<br>For children from 1 month to less than 3 years of age: crush the half tablet and mix with a teaspoon of jam, honey or yoghurt.<br><br>For children from 3 to 12 years of age: crush one tablet and mix with a teaspoon of jam, honey or yoghurt.<br>For adults, elderly and children over 12 years of age: swallow the two tablets with water; if this is difficult, crush the tablets as above.</td></tr>
<tr><td>Dose and frequency of administration</td><td>Where possible, the dose should be administered shortly before exposure or as soon as possible after an exposure has occurred but not once 24 hours has passed.
<table>
<tr><th></th><th>Tablets</th><th>Iodine equivalent</th></tr>
<tr><td>Adults, elderly, and children over 12 years of age</td><td>2 tablets</td><td>100mg</td></tr>
<tr><td>Children (from 3 to 12 years of age)</td><td>1 tablet</td><td>50mg</td></tr>
<tr><td>Children (from 1 month to less than 3 years of age)</td><td>½ tablet</td><td>25mg</td></tr>
<tr><td>Neonates (from birth to less than 1 month of age)</td><td>¼ tablet</td><td>12.5mg</td></tr>
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| **Duration of treatment** | A single dose to be administered immediately. This will protect against exposure lasting up to 24 hours. |
| **Quantity to be supplied/ administered** | A single dose |
| **Storage** | Store in original container below 25 $^{o}$C |
| **Disposal** | Any unused product or waste material should be disposed of in accordance with local arrangements. |
| **Drug Interactions** | The SPC lists drug interactions; these are not contraindications to administering potassium iodate. Where advice is given by the appropriate public health authority that potassium iodate should be taken, the benefit of taking this medicine outweighs the risk of the interactions.<br><br>Refer to the SPC for a complete list. |
| **Identification & Management of Adverse Reactions** | The risk of adverse reactions such as nausea and taste disturbances, particularly to a single dose, is remote.<br><br>Where advice is given by the appropriate public health authority that potassium iodate should be taken, the benefit of taking this medicine outweighs the risk of undesirable effects.<br><br>A detailed list of adverse reactions is available in the SPC.<br>In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a telephone must be available for immediate use.<br><br>In case of anaphylaxis:<br>• Refer to adrenaline (epinephrine) PGD and anaphylaxis policy<br>• Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E<br>• Ensure reaction is fully documented in patient notes<br>• Ensure all patient records are marked **ALLERGIC Potassium Iodate**.<br>• The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers |
| **Reporting procedure of** | All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow Card scheme or search for MHRA Yellow Card in the |

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| **Adverse Reactions** | Google Play or Apple App Store.<br><br>Report via Once for Wales Reporting System.<br>Alert the supervising doctor in the event of serious adverse reaction. |
| **Written information to be given to patient or carer** | Supply pre-labelled pack(s) of tablets.<br><br>The marketing authorisation holder's patient information leaflet (PIL) does not need to be given when a product is administered. However, if available, it would be good practice to supply the PIL.<br><br>Give appropriate advice if the medication is used off-label. Write the patients name and the date of supply onto the label. Draw patient's or representative's attention to the label and patient information leaflet.<br><br>Provide the PHE/UKHSA Potassium Iodate Information Leaflet if available. |
| **Patient advice/Follow up treatment** | Explain why the treatment is necessary.<br><br>Inform the individual or their carer of possible side effects and their management. Ensure the individual is aware medical advice should be sought if side effects or any other unexplained effects on health are experienced. Contact GP via surgery or emergency on call service.<br><br>Advise individuals who are in the last three months of pregnancy to make an appointment to see their GP or midwife. When a mother has taken potassium iodate tablets in the last three months of pregnancy, umbilical cord blood samples should be taken at birth for the baby's thyroid hormone measurement.<br><br>Advise parents or carers of babies under three months old, to make an appointment to see their GP or midwife. It is important to check the thyroid hormone levels of young babies after being given potassium iodate.<br><br>Adults with previously treated or active thyroid disease should consult their GP if they notice any change in their condition. Other individuals will not need to see their GP after taking the tablets. However, advise if they have to see their GP for other reasons, they should tell the GP they have taken potassium iodate tablets. |

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| **Special Considerations/ Additional Information** | The risk of health problems occurring, particularly to a single dose, is remote. The special precautions listed in the SPC have been considered but the UKHSA has determined the benefit outweighs the risk, where advice is given by the appropriate public health authority that potassium iodate should be taken.<br>Iodine is actively transported in breast milk; however, the dosage in breast milk is insufficient on its own to protect babies. Therefore, breast-feeding mothers should continue to breast-feed their babies, and these babies should also receive potassium iodate in the normal dose by age (see Dose and frequency of administration) |
| **Records** | Record consultation details as required by local procedures.<br>In addition, record:<br>• That valid informed patient consent to treatment was obtained or a decision to treat was made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent, if appropriate. Record advice given and action taken if patient excluded or declines treatment.<br>• If individual was not treated under PGD record action taken<br>• Name of individual, address, date of birth, GP contact details where appropriate.<br>• Any reasons for exclusion or referral, including actions taken.<br>• Medical and drug history taken, including any known allergies or previous adverse events and nature of reaction<br>• Printed name and signature of registered health professional responsible for administration or supply<br>For administration, record:<br>• Date and time of administration<br>• Name, form, strength and dose of drug administered<br>• Route of administration<br>• Batch number and Expiry date<br>• Details of any adverse reactions and actions taken<br>For supply, record:<br>• Date and time of supply<br>• Name, form, strength, dose, frequency, and quantity of medication supplied<br>• Batch number and expiry date of medicine supplied<br>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns, including advice given if excluded or declines treatment<br>• Details of any adverse drug reactions and actions taken<br>• Any advice received from medical cover and advice given to patient / carer.<br>• Record that medication was administered/supplied via Patient Group Direction (PGD), record PGD title and version number |

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| | Records should be signed and securely kept for a defined period in line with local policy.<br><br>All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.<br><br>Document according to local policy. |

## 5. Key references.

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| **Key references** | • Potassium iodate 85mg tablets Summary of Product Characteristics updated 9 March 2016<br>• Potassium iodate 85mg Patient Information Leaflet updated 9 March 2016<br>• PHE Potassium iodide Information leaflet 31 January 2015<br>• The Human Medicines (Amendment) Regulations 2018 No.199 Iodine thyroid blocking: Guidelines for use in planning and responding to radiological and nuclear emergencies World Health Organization 2017<br>• Chemical, biological, radiological and nuclear incidents: clinical management and health protection CBRN Handbook 2018<br>• When Patient Group Directions (PGDs) are not required. Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines updated 24 March 2021 |

## Appendix A Staff accredited to use this Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it.

Practitioner: *By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct*.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

| Name of health professional | Signature | Senior representative authorising health professional | Date |
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The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.

The healthcare professional should retain a copy of the document after signing.