**Publications Reference:** **B1235**

**Protocol for the administration of potassium iodide tablets**

Protocol for the administration of potassium iodide 65mg tablets to adults and children exposed to or at risk of exposure to radioactive iodine in an emergency situation

Reference: 20211214PotassiumIODIDEprotocol

Version no: 02.00

Valid from: 14 December 2021

Review date: 14 December 2023

Expiry date: 13 December 2024

**The UK Health Security Agency (UKHSA) has developed this protocol to facilitate the administration of potassium iodide in an emergency situation**

This protocol has been prepared for the administration of a Pharmacy only (P) medication, for which a Patient Group Direction is not required. This protocol is intended to support healthcare practitioners who have been appropriately trained and authorised by the service provider to work under this protocol.

There is no legal requirement for formal authorisation of a protocol. The protocol may be adopted by commissioners and providers to support the administration of the named medicine. It should be approved through local governance processes prior to use.

**The clinical contents should not be amended.**

Any queries regarding the content of this protocol should be addressed to: [NSAC@phe.gov.uk](mailto:NSAC@phe.gov.uk)[[1]](#footnote-1)

**Change history**

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| **Version Number** | **Change details** | **Date** |
| 01.00 | New PHE protocol for Potassium iodide | 10 December 2018 |
| 02.00 | 1. Anaphylaxis, severe allergy or sensitivity to any of the excipients in the tablets and dermatitis herpetiformis or hypocomplementaemic vasculitis added to criteria for exclusion 2. Renal disease removed from criteria for exclusion 3. Off-label use: addition that 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. 4. Additional information under method of administration 5. Drug interactions, patient advice, special considerations and recording requirements sections amended 6. Change from PHE to UKHSA; standard wording changes in line with UKHSA protocols; references updated | 14 December 2021 |

1. **Protocol Development**

This protocol has been developed by the following on behalf of the UKHSA:

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

**Expert Panel**

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| --- | --- |
| **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 | Senior 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 Haematooncolgy Cancer Centre London  Chairman Conservative Health  Co-Chair European Blood and Marrow Transplant Nuclear Accident Committee  Co-Chair Global Emergency Nuclear Accident WBMT Society |
| Craig Prentice | Advanced Paramedic Practitioner, Surrey and Sussex Healthcare NHS Trust |

#### Characteristics of Staff

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| **Qualifications and professional registration** | This protocol is intended for use by healthcare practitioners who have been appropriately trained and authorised by the service provider to work under this protocol |

1. **Clinical condition or situation to which this protocol applies.**

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| **Clinical condition or situation to which this protocol applies** | Known or suspected exposure to radioactive iodine or at risk of exposure, in an emergency situation. |
| **Criteria for inclusion** | All age groups (adults, including pregnant or breast-feeding individuals, children, babies and neonates):  1. With known or suspected imminent exposure to radioactive iodine or at risk of exposure  2. As a precautionary countermeasure as declared by the UKHSA  Note: Pregnant and breast-feeding individuals, neonates, infants and children are a priority for treatment. Prophylactic administration of potassium iodide to pregnant individuals is also effective in protecting the thyroid of the foetus. |
| **Criteria for exclusion** | Individuals are excluded from this protocol if:   1. 24 hours or more has passed since the known or suspected exposure to radioactive iodine 2. They have experienced anaphylaxis, severe allergy or sensitivity to any iodine containing medicines or any of the excipients in the tablets 3. They have dermatitis herpetiformis or hypocomplementaemic vasculitis   Pregnancy and hyperthyroidism are **not** exclusion criteria[[2]](#footnote-2). |
| **Action to be taken if the patient is excluded** | Explain why they have been excluded and refer the individual to the supervising doctor.  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** | Advise the individual or their carer of the possible consequences of refusing treatment and about its protective effects.  Refer the individual to the supervising doctor. |

1. **Description of Treatment**

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| **Name, strength & formulation of drug** | Potassium iodide 65mg tablets equivalent to 50mg of iodine |
| **Legal category** | Pharmacy only (P) medicine |
| **Black Triangle▼** | No |
| **Off-label use** | Yes  Although the Summary of Product Characteristics (SPC) states treatment should be initiated within one hour of exposure, 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.  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.  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. |
| **Route/method of administration** | Oral  For neonates (from birth to up to 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.  For children from 1 month to 3 years of age: crush the half tablet and mix with a teaspoon of jam, honey or yoghurt.  For children from 3 to 12 years of age: crush one tablet and mix with a teaspoon of jam, honey or yoghurt.  For adults, elderly and children from 12 years of age: swallow the two tablets with water; if this is difficult, crush the tablets as above |
| **Dose and frequency of administration** | 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. .   |  |  |  | | --- | --- | --- | |  | Tablets | Iodine equivalent | | *Adults, elderly and children from 12 years of age* | 2 tablets | 100mg | | *Children (from 3 to12 years of age)* | 1 tablet | 50mg | | *Children (from 1 month to*  *3 years of age)* | ½ tablet | 25mg | | *Neonates (from birth up to 1 month of age)* | ¼ tablet | 12.5mg | |
| **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 oC |
| **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 iodide. Where advice is given by the appropriate public health authority that potassium iodide should be taken, the benefit of taking this medicine outweighs the risk of the interactions.  Refer to the [SPC](https://www.medicines.org.uk/emc/product/3019/smpc) 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.  Where advice is given by the appropriate public health authority that potassium iodide should be taken, the benefit of taking this medicine outweighs the risk of undesirable effects.  A detailed list of adverse reactions is available in the [SPC](https://www.medicines.org.uk/emc/product/3019/smpc) |
| **Reporting procedure of Adverse Reactions** | All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the [Yellow Card scheme](https://yellowcard.mhra.gov.uk/) or search for MHRA Yellow Card in the Google Play or Apple App Store.  Alert the supervising doctor in the event of serious adverse reaction. |
| **Written information to be given to patient or carer** | 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.  Provide the [PHE/UKHSA Potassium Iodide Information Leaflet](https://www.nhsggc.org.uk/media/239847/potassium-iodide-2016-lefalet.pdf) if available. |
| **Patient advice/Follow up treatment**  Continued overleaf  **Patient advice/Follow up treatment**  (continued) | Explain why the treatment is necessary.  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.  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 iodide tablets in the last three months of pregnancy, umbilical cord blood samples should be taken at birth for the baby’s thyroid hormone measurement.  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 iodide.  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 iodide tablets. |
| **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 iodide should be taken.  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 iodide in the normal dose by age (see [Dose and frequency of administration](#dose)) |
| **Records** | Document according to local policy.  Records normally include:   * whether valid informed consent was given or a decision to supply was made in the individual’s best interests in accordance with the [Mental Capacity Act 2005](https://www.legislation.gov.uk/ukpga/2005/9/contents) * name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) * name of member of staff who administered the product * name and brand of product * date of administration * dose, form and route of administration of product * quantity supplied * batch number and expiry date * advice given including advice given if excluded or declines treatment * details of any adverse drug reactions and actions taken * record supplied via protocol * records should be signed and dated   All records should be clear, legible and contemporaneous.  A computerised or manual record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

#### Key References

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| **Key references** | * [Potassium iodide 65mg tablets Summary of Product Characteristics](https://www.medicines.org.uk/emc/product/3019/smpc) updated 26 May 2020 * [Potassium iodide 65mg tablets Patient Information Leaflet](https://www.medicines.org.uk/emc/product/3019/pil) updated 26 May 2020 * [PHE Potassium iodide Information leaflet](https://www.nhsggc.org.uk/media/239847/potassium-iodide-2016-lefalet.pdf) 31 January 2015  * [The Human Medicines (Amendment) Regulations 2018 No.199](https://www.legislation.gov.uk/uksi/2018/199/made?view=plain) * [Iodine thyroid blocking: Guidelines for use in planning and responding to radiological and nuclear emergencies](https://www.who.int/publications/i/item/9789241550185) World Health Organization 2017 * [Chemical, biological, radiological and nuclear incidents: clinical management and health protection](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/712888/Chemical_biological_radiological_and_nuclear_incidents_clinical_management_and_health_protection.pdf) CBRN Handbook 2018 * [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](file:///C:\Users\jackie.lamberty\Documents\PHE\PGDs\PGD%20templates\CBRN\potassium%20iodate%20%20iodide\2021%20review\•%09https:\www.sps.nhs.uk\wp-content\uploads\2019\03\SPS-When-PGDs-should-not-be-used-V1.3-March-21.pdf) updated 24 March 2021 |

1. Note: UKHSA email addresses not changed from @phe.gov.uk at the time of writing this protocol [↑](#footnote-ref-1)
2. If pregnant individuals with active hyperthyroidism take potassium iodide 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. [↑](#footnote-ref-2)