**Publications Gateway Reference:** [GW-159](https://digitaltools.phe.org.uk/browse/GW-159)

## Protocol

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 no: 20181210 Potassium iodide protocol

Version no:01.00

Valid from: 10 December 2018

Review date: 10 December 2020

Expiry date: 10 December 2021

**Public Health England has developed this protocol to facilitate the administration of potassium iodide in an emergency situation**

This protocol has been prepared by the UK National Countermeasure Team for the administration of a Pharmacy only (P) medication, for which a Patient Group Direction is not required.

There is no legal requirement for formal authorisation of a protocol. The protocol may be adopted by commissioners and providers to support practitioners.

NMC Standards for Medicines Management require that NMC registrants must only supply and administer medicinal products in accordance with set processes. This protocol is intended to support nurses and other healthcare practitioners in the administration of this ‘P’ medicine.

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

1. **Protocol Development**

This protocol has been developed by the following on behalf of Public Health England:

|  |  |
| --- | --- |
| **Developed by:** | **Name** |
| Pharmacist (Lead author) | Judith Field  UK National Countermeasure Manager  Emergency Response Department  Public Health England |
| Doctor | Nick Gent  Consultant in Health Protection  Emergency Response Department  Public Health England |
| Registered Nurse | Joanne Bosanquet  Deputy Chief Nurse  Public Health England |

**Expert Panel**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| John Simpson | Chair, Expert Panel  Director of Emergency Preparedness, Resilience and Response  Public Health England |
| Jacqueline Lamberty | Lead Pharmacist Medicines Management Services  Public Health England |
| Sally Millership | Consultant in Communicable Disease Control  Public Health England East of England |
| Andrew Simpson | Consultant Medical Microbiologist  Public Health England |
| Duncan Cox | Specialist Radiation Protection Scientist  Public Health England |

#### Characteristics of Staff

|  |  |
| --- | --- |
| **Qualifications and professional registration** | This protocol is intended for use by healthcare practitioners eg nurses currently registered with the Nursing and Midwifery Council (NMC), pharmacists currently registered with the General Pharmaceutical Council (GPhC), additional registered healthcare practitioners |

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

|  |  |
| --- | --- |
| **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 ie adults, including pregnant and lactating women, 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 PHE  Note: Pregnant and lactating women, neonates, infants and children are a priority for treatment. Prophylactic administration of potassium iodide to the pregnant mother is also effective in protecting the thyroid of the foetus. |
| **Criteria for exclusion** | Individuals with known:   * anaphylaxis, severe allergy or sensitivity to any iodine containing medicines * renal failure   Pregnancy and hyperthyroidism are **not** exclusion criteria[[1]](#footnote-1). |
| **Cautions including any relevant action to be taken** | None |
| **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 either need to provide a Patient Specific Direction or administer the medicine themselves. |
| **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. |
| **Arrangements for referral for medical advice** | As per local policy |

1. **Description of Treatment**

|  |  |
| --- | --- |
| **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 that 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 to be decided according to local advice at the time of an incident.  Where a product is recommended off-label consider, as part of the consent process, informing the individual/carer that the product is being offered in accordance with national guidance but that this is outside the product licence. |
| **Route/method of administration** | Oral  The dose may be crushed and mixed with milk, water or fruit juice, honey, jam or yoghurt before administration |
| **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. | Tablets | Iodine equivalent | | *Adults, elderly and adolescents (over 12 years)* | 2 tablets | 100mg | | *Children (3-12 years)* | 1 tablet | 50mg | | *Children (1 month to*  *less than 3 years)* | ½ tablet | 25mg | | *Neonates (birth to less than 1 month)* | 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** | As above |
| **Storage** | Store in original container below 25 oC  Store out of reach and sight of children |
| **Disposal** | Any unused product or waste material should be disposed of in accordance with local requirements. |
| **Drug Interactions** | The following interactions may occur, but are not contraindications to giving potassium iodide. Where advice is given by the appropriate public health authority that potassium iodide should be taken then the benefit of taking this medicine outweighs the risk of the interactions given overleaf:   * medicines such as captopril and enalapril can cause hyperkalaemia. This effect may be enhanced with the use of potassium iodide * the effect of quinidine on the heart is increased by increased plasma concentration of potassium * hyperkalaemia results from the interaction between potassium salts and potassium-sparing diuretics such as amiloride or triamterene or aldosterone antagonists   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, particularly to a single dose, is remote.  Where advice is given by the appropriate public health authority that potassium iodide should be taken, then 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/).  Medical staff should also be informed. |
| **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.  A special Public Health England leaflet, “[Potassium iodide tablets](http://www.nhsggc.org.uk/media/239847/potassium-iodide-2016-lefalet.pdf)”, in addition to the PIL, has been developed for giving to all individuals at the time of treatment. |
| **Patient advice/Follow up treatment** | Explain why the treatment is necessary.  Advise that the dose may be crushed and mixed with milk or water, juice, jam, honey or yogurt before administration if appropriate.  Inform the individual or their carer of possible side effects and their management. Ensure the individual is aware that medical advice should be sought if side effects or any other unexplained effects on health are experienced.  All pregnant women in their third trimester and those with babies aged less than 1 month should advise their GP and midwife so umbilical cord blood/blood samples can be tested after birth for TSH hormone levels and if raised, T4 levels in the baby.  If stable iodine is given to neonates close follow up of thyroid function is essential. For neonates who have been administered potassium iodide in the first few weeks of life, TSH levels and if necessary T4 levels should be monitored and appropriate replacement therapy given.  Adults with previously treated or active thyroid disease should consult their GP if they notice any change in their condition.  Other individuals do not need to consult their GP unless they notice any change in their condition. If they consult their GP for any reason, they should mention that they have received potassium iodide treatment. |
| **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 PHE has determined the benefit outweighs the risk, where advice is given by the appropriate public health authority that potassium iodide should be taken.  Throughout pregnancy the number of doses of potassium iodide should be kept to a minimum and in iodine deficiency prolonged dosage could lead to maternal or foetal thyroid blockage with possible consequences for foetal development, but this protocol is for administration of a single dose.  If potassium iodide is administered late in pregnancy, the thyroid function of the new-born should be monitored. This is generally met by routine screening in the neonatal period; great care should be taken to ensure that this screening is performed and reported promptly as soon as possible after birth.  For neonates who have been administered potassium iodide in the first few weeks of life thyroid-stimulating hormone (TSH) levels and, if necessary, T4 levels should be monitored and appropriate replacement therapy given.  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 given above. |
| **Records** | Document in the record that potassium iodide was administered in accordance with this protocol.  All records should be clear, legible and contemporaneous. |

#### Key References

|  |  |
| --- | --- |
| **Key references** | * Potassium iodide 65mg tablets Summary of Product Characteristics [www.medicines.org.uk/emc/](http://www.medicines.org.uk/emc/) * WHO guidance <http://www.who.int/ionizing_radiation/pub_meet/iodine-thyroid-blocking/en/> * NRPB guidance <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/425072/Documents_of_the_NRPB_Volume_12_Number_3.pdf> * CBRN Handbook <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> |

1. If pregnant women with active hyperthyroidism take potassium iodide there is a risk of foetal thyroid blockage. However this contraindication has not been included because hypothyroidism is screened post-natally in the UK. [↑](#footnote-ref-1)