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Protocol for the administration of potassium iodate tablets

Protocol for the administration of potassium iodate 85mg tablets to adults and children exposed to or at risk of exposure to radioactive iodine in an emergency situation

Reference no:	20241201PotassiumIODATEprotocol
Version no:	3.00
Valid from:	1 December 2024
Review date:	1 December 2026
Expiry date:	1 December 2027

The UK Health Security Agency (UKHSA) has developed this protocol to facilitate the administration of potassium iodate 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 individuals 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: sma@ukhsa.gov.uk

Change history

Version Number	Change details	Date
1.00	New PHE protocol for Potassium iodate	10 December 2018
2.00	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
2.00a	Correction of typo on page 8: 'PGD' changed to 'Protocol'	19 January 2022
2.00b	Update to contact details on page 1	24 April 2022
3.00	1. Standard wording changes in line with UKHSA protocols; references updated 2. Change to wording on page 1: "healthcare practitioners" changed to individuals 3. Qualifications and professional registration: wording changed to expand to all individuals with some examples provided 4. "They have not given consent to take potassium iodate" added to exclusion criteria 5. "doctor" changed to prescriber throughout 6. Arrangements for referral for medical advice and Cautions including any relevant action to be taken sections added as per UKHSA protocol template and information previously in footnote moved to cautions and renal failure added to cautions 7. Off-label use: one hour changed to three hours as per SPC and information on renal failure added 8. Route/method of administration: juice changed to water for administration to neonates, addition of swallow whole for children who can, change to advice regarding honey, jam and yoghurt 9. Potassium iodate content added to dosing table and method of administration instructions 10. "Special considerations/additional information" section removed and information moved to cautions 11. Records section amended to remove list of what is normally included	1 December 2024

1. Protocol Development

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

Developed by:	Name
Pharmacist (Lead author)	Anna Wilkinson, Clinical Response Pharmacist, UKHSA
Doctor	Kiran Attridge, Senior Medical Adviser and Consultant in Public Health, UKHSA
Registered Nurse	Gemma Hudspeth, Senior Health Protection Practitioner, UKHSA

Expert Panel

Name	Designation
Ruth Milton	Head of Clinical and Public Health Response (advice), UKHSA
Duncan Cox	Specialist Radiation Protection Scientist, UKHSA
Sharon Ely	Radiation Protection Specialist, UKHSA
Jo Jenkins	Lead Pharmacist, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol, North Somerset and South Gloucestershire ICB
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Prof. Ray Powles	Head Haematooncology Cancer Centre, London. Co-chair European Blood and Marrow Transplant Nuclear Accident Committee Co-chair Global Emergency Nuclear Accident WBMT Society
Craig Prentice	Consultant Practitioner Paramedic, Surrey and Sussex Healthcare NHS Trust

2. Characteristics of Staff

Qualifications and professional registration	This protocol is intended for use by individuals who have been appropriately trained and authorised by the service provider to work under this protocol. This may include: • healthcare practitioners • individuals listed in Part 1 or 2 of Schedule 1 to the Civil Contingencies Act 2004 • individuals working in accordance with an off-site emergency plan prepared under the Radiation (Emergency Preparedess and Public Information) Regulations 2019 • other individuals authorised by the service provider according to local governance frameworks

3. 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 (adults, including pregnant or breastfeeding 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 breastfeeding 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.
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 (see Summary of Product Characteristics (SPC) for details) 3. They have dermatitis herpetiformis or hypocomplementaemic vasculitis 4. They do not give consent to take potassium iodate
Cautions including any relevant action to be taken (continued overleaf)	The risk of health problems occurring, particularly to a single dose, is remote. The special precautions listed in the SPC have been considered. 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. **Pregnant individuals with active hyperthyroidism** If pregnant individuals with active hyperthyroidism take potassium iodate, there is a risk of foetal thyroid blockage. This

Cautions including any relevant action to be taken (continued)	contraindication is not an exclusion because post-natal screening for hypothyroidism is undertaken in the UK. **Breastfeeding** Iodine is actively transported in breast milk; however, the dosage in breast milk is insufficient on its own to protect babies. Therefore, breastfeeding individuals should continue to breastfeed their babies, and these babies should also receive potassium iodate in the normal dose by age (see Dose and frequency of administration) **Renal failure** Advise individuals to contact their specialist for advice on any monitoring requirements needed following administration.
Action to be taken if the individual is excluded	Explain why they have been excluded and refer the individual to the supervising prescriber If the supervising prescriber decides the product can be administered, they will need to provide a Patient Specific Direction.
Action to be taken if the individual 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 prescriber.

4. Description of Treatment

Name, strength and formulation	Potassium iodate 85mg 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 three hours 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. Using potassium iodate in renal failure is off-label. Although the SPC states that renal failure is a contraindication, benefit is thought to outweigh the risk when only one dose is administered. See cautions for advice for individuals with renal failure. Where a product is recommended off-label consider, as part of the consent process, informing the individual or their carer the product is being offered in accordance with national guidance but this is outside the product licence.

<table>
<tr><td>Route / method of administration</td><td>Oral

For neonates (from birth up to 1 month of age): crush the quarter tablet (21.5mg) and dissolve it in a small quantity of milk or water. Shake well to make sure the powder dissolves.

For babies and children from 1 month to 3 years of age: crush the half tablet (42.5mg) and mix with milk, water or juice (if over 6 months).

For children from 3 to 12 years of age: crush one tablet (85mg) and mix with milk, water or juice. If the child is able, the tablet can be swallowed whole.

For children, tablets can also be crushed and mixed with jam, honey (if over 1 year old) or yoghurt

For adults and children from 12 years of age: swallow the two tablets (170mg) 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><td></td><td>Tablets (potassium iodate content)</td><td>Iodine equivalent</td></tr><tr><td>Adults and children (over 12 years)</td><td>2 tablets (170mg)</td><td>100mg</td></tr><tr><td>Children (3-12 years)</td><td>1 tablet (85mg)</td><td>50mg</td></tr><tr><td>Children (1 month to less than 3 years)</td><td>½ tablet (42.5mg)</td><td>25mg</td></tr><tr><td>Neonates (birth to less than 1 month)</td><td>¼ tablet (21.5mg)</td><td>12.5mg</td></tr></table></td></tr>
<tr><td>Duration of treatment</td><td>A single dose to be administered immediately. This will protect against exposure lasting up to 24 hours.</td></tr>
<tr><td>Quantity to be supplied/ administered</td><td>A single dose</td></tr>
<tr><td>Storage</td><td>Store in original container below 25 ^{o}C</td></tr>
<tr><td>Disposal</td><td>Any unused product or waste material should be disposed of in accordance with local arrangements.</td></tr>
<tr><td>Drug interactions</td><td>The SPC lists very limited 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, as the benefit of taking this medicine outweighs the risk of the interactions.

Refer to the SPC for a complete list</td></tr>
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Identification and 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 iodate 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
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 or search for MHRA Yellow Card in the Google Play or Apple App Store. Alert the supervising prescriber in the event of serious adverse reaction.
Written information to be given	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.
Advice/follow up treatment	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 an individual 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. 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. Advise individuals who are breastfeeding that they can continue to breastfeed following administration of potassium iodate. 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 or other healthcare professional for other reasons, they should tell them they have taken potassium iodate tablets.
Records	Record and retain information according to local policies

5. Key References

Key references	• Potassium iodate 85mg tablets Summary of Product Characteristics updated 9 March 2016 • Potassium iodate 85mg Patient Information Leaflet updated 8 March 2016 • 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 • When not to use a PGD updated 2 July 2024