UK Health Security Agency

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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:	02.00b
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: sma@ukhsa.gov.uk

Change history

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
02.00a	Correction of typo on page 8: 'PGD' changed to 'Protocol'	19 January 2022
02.00b	Update contact details on page 1	24 April 2023

1. Protocol Development

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

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

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

2. Characteristics of Staff

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

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 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[1].
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] 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.

4. Description of Treatment

<table>
<tr><td>Name, strength & formulation of drug</td><td>Potassium iodide 65mg tablets equivalent to 50mg of iodine</td></tr>
<tr><td>Legal category</td><td>Pharmacy only (P) medicine</td></tr>
<tr><td>Black Triangle▼</td><td>No</td></tr>
<tr><td>Off-label use</td><td>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.</td></tr>
<tr><td>Route/method of administration</td><td>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</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</td><td>Iodine equivalent</td></tr>
<tr><td>Adults, elderly and children from 12 years of age</td><td>2 tablets</td><td>100mg</td></tr>
<tr><td>Children (from 3 to12 years of age)</td><td>1 tablet</td><td>50mg</td></tr>
<tr><td>Children (from 1 month to 3 years of age)</td><td>½ tablet</td><td>25mg</td></tr>
<tr><td>Neonates (from birth up to 1 month of age)</td><td>¼ tablet</td><td>12.5mg</td></tr>
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</td></tr>
</table>

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 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 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
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 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 if available.
Patient advice/Follow up treatment Continued overleaf	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.

Patient advice/Follow up treatment (continued)	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)
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 • 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 Protocol should also be kept for audit purposes in accordance with local policy.

6. Key References

Key references	• Potassium iodide 65mg tablets Summary of Product Characteristics updated 26 May 2020 • Potassium iodide 65mg tablets Patient Information Leaflet updated 26 May 2020 • PHE Potassium iodide Information leaflet 31 January 2015 • 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 • Chemical, biological, radiological and nuclear incidents: clinical management and health protection 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 updated 24 March 2021