Patient Group Direction (PGD) template

Supply of potassium iodide 65mg tablets to adults and children exposed to radioactive iodine, or at risk of exposure

Version no: 2014/1
Valid from: 2nd July 2014
Review date: 2nd July 2015
Expiry date: 2nd July 2016

Public Health England is not a legal authority for the authorisation of PGDs.

Each organisation using this PGD must ensure that it is formally authorised and signed by a pharmacist, medical lead and governance lead for the organisation so that this document meets legal requirements for a PGD. The PGD is not legal or valid without this local, formal authorisation.

THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

This Patient Group Direction template has been produced by Public Health England to assist organisations such as NHS England Area Teams or others to develop and authorise a PGD that is consistent with current national guidance.

1. Clinical situation

Situation	Known or suspected exposure to radioactive iodine
Inclusion Criteria	Adults children, babies and neonates with known or suspected exposure to radioactive iodine. All age groups including pregnant women and lactating women, who should receive the normal adult dosage.
Exclusion Criteria[1]	Those with known: • iodine sensitivity • hypocomplementaemic vasculitis • dermatitis herpetiformis • renal failure Pregnancy and hyperthyroidism are not exclusion criteria.

Action if Excluded	Explain why they have been excluded and refer the patient to the supervising doctor.
Action if Patient Declines	Refer the patient to the supervising doctor.
Additional information	Pregnant and lactating women, neonates, infants and children should be treated first. Prophylactic administration of potassium iodide to the pregnant mother should also be effective for the foetus. The potential benefit of iodine prophylaxis is greatest in the young. The thyroid of the foetus, neonate and young infant has a higher yearly thyroid cancer risk per unit dose of radioactive iodine than the thyroid of an adult. Neonates in the first days of life are at particular risk from exposure to radioactive iodine and blocking of thyroid function by overload of potassium iodide. The fraction of radioactive uptake is fourfold greater than all other age groups. The neonatal thyroid is especially sensitive to functional blocking caused by overload of potassium iodide. Transient hypothyroidism during this early period of brain development can result in loss of intellectual capacity.

2. Description of Treatment

[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.

Name of Medicine	Potassium iodide		
Legal status	Pharmacy only (P) medicine		
Formulation and Strength	65mg tablets equivalent to 50mg of iodine		
Route of administration	Oral. For neonates the dose may be crushed and mixed with milk or water before administration. For babies the dose may be crushed and mixed with milk or juice before administration. For children the dose may be crushed and mixed with e.g. jam, honey or yoghurt.		
Dose	Where possible, the dose should be administered before exposure, or as soon as possible after an exposure has occurred.	<u>Tablets</u>	<u>Iodine equivalent</u>
	Adults, elderly and adolescents (over 12 years)	2 tablets	100mg
	Children (3-12 years)	1 tablet	50mg
	Children (1 month – 3 years)	½ tablet	25mg
	Neonates (birth – 1 month)	¼ tablet or 12.5mg iodine equivalent as standard solution	12.5mg
Frequency of administration	A single dose to be administered. This will protect against exposure lasting up to 24 hours.		

Total number of doses to be supplied	One
Black Triangle ▼	No
Is the use outwith the SPC?	Yes
Storage requirements	Store in original container below 25 ^{o}C Store out of reach and sight of children

Interaction with other medicinal products	The following interactions may occur, but are not contraindications to giving potassium iodide; and where advice is given by the appropriate public health authority that potassium iodate should be taken then the benefit of taking this medicine outweighs the risk of interactions given below: 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
Undesirable effects	The risk of adverse reactions, particularly to a single dose, is remote; and where advice is given by the appropriate public health authority that potassium iodate should be taken then the benefit of taking this medicine outweighs the risk of undesirable effects given below: Hypersensitivity reactions e.g. skin rashes, swollen salivary glands, headache, bronchospasm and gastro-intestinal disturbances can be mild or severe and may be dose dependent. Hyperthyroidism, iodine induced autoimmunity (Grave's and Hashimoto type), toxic nodular goitre and iodine-induced hypothyroidism have been reported. An overactive thyroid gland, thyroiditis and an enlarged thyroid gland with or without development or myxoedema have also been reported. Continued administration may lead to mental depression, nervousness, sexual impotence and insomnia
Additional warnings	The risk of these additional health problems occurring, particularly to a single dose, is remote; and where advice is given by the appropriate public health authority that potassium iodate should be taken then the benefit of taking this medicine outweighs the risk of the conditions given below from occurring: • Patients with thyrotoxicosis treated medically, or patients with a past history of thyrotoxicosis treated medically who are now off treatment and apparently in remission, may be at risk. • Iodine induced hyperthyroidism may be precipitated in patients with asymptomatic nodular goitre or latent Graves` disease, who are not under medical care.

	• Potassium salts should be given cautiously to patients with renal or adrenal insufficiency, acute dehydration or heat cramp. The effect of quinidine on the heart is increased by increased plasma concentration of potassium.
Reporting procedure for adverse reactions	All suspected adverse reactions in children and severe adverse reactions in adults should be reported using the Yellow card system on http://yellowcard.mhra.gov.uk/ Any serious adverse reaction to the drug should be documented in the individual's record. Medical staff should also be informed.
Patient Information (written)	Manufacturer's Patient Information Leaflet (PIL) should be provided with the medicine A special, leaflet, in addition to the PIL, has been developed for giving to all patients at the time of treatment.
Follow-up	• Ideally, contact details of the patient should be recorded. • All pregnant women in their third trimester and those with babies aged under 1 month should advise their GP and midwife so that umbilical cord blood/blood samples can be tested for TSH hormone levels after birth, and, if raised, T4 levels in the baby. • Adults with previously treated or active thyroid disease should consult their GP if they notice any change in their condition. • Other patients 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. • 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.
Additional information	Throughout pregnancy the number of doses of potassium iodide should be kept to a minimum. In iodine deficiency prolonged dosage could lead to maternal or foetal thyroid blockage with possible consequences for foetal development. 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– however great care should be taken to ensure that this screening is performed and reported promptly as soon as

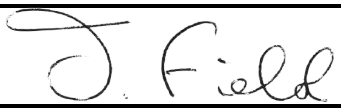
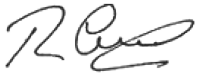
	possible after birth. For neonates who have been administered potassium iodide in the first few weeks of life TSH levels and, if necessary, T4 levels should be monitored and appropriate replacement therapy given. Iodine is actively transported in breast milk. However, the dosage in breast milk is insufficient on its own to protect babies. Therefore, those breast feeding mothers should continue to breast feed their babies, and these babies should also receive potassium iodate medicine as per the normal dose by age given above.
Record/Audit Trail	There must be appropriate records kept and maintained by the approved practitioner to enable verification of service provision and training requirements, and provide information for internal and external audit and evaluation purposes. In all cases where a supply is made, manual records, computer records and data collection should include as a minimum the following information: - Patient's name, address and date of birth - Name of medicine - Dose and form supplied - Date supplied and by whom - If possible, record the whereabouts of the individual during 6 hours prior to treatment (for better estimation of exposure). - GP's name
References/Resources and comments:	Potassium iodide tablets 65mg Summary of Product Characteristics http://www.medicines.org.uk/emc/medicine/27530/SPC/ThySat+65+mg+tablets/

3. Characteristic of Staff authorised under the PGD

Qualifications required	• Pharmacist, registered nurse. • (Additional healthcare workers may be identified by the Medical Director of the Trust, Director of Public Health Medicine or nominated deputy).
Additional requirements	• To be authorised by name as an approved practitioner under the current terms of this Patient Group Direction (PGD) before working to it; • To have undertaken appropriate training for working under a PGD for supply of medicines; • To have undertaken training appropriate to this PGD.
Continued training requirements	Training in the management of emergency situations following the release of, or the potential release of radioactive iodine.

4. PGD Development

PGD developed, peer reviewed and ratified by the following on behalf of Public Health England:

Developed & produced by:	**Name**	**Date**
Pharmacist		2nd July 2014
Doctor (Lead Author)		2nd July 2014
Representative of the healthcare professionals who will work to this PGD	Rosie Furner	

Acknowledgements

Name	**Designation**

5. ORGANISATIONAL AUTHORISATIONS

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

Complete details below or use format agreed according to local policy.

Organisation Approvals		DATE
Lead Doctor		
Lead Pharmacist		
Local Clinical Governance Committee e.g. DTC/MMT or equivalent		
Additional signatories according to local policy e.g. independent contractor providers.		

Organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy but this should be a signature list or an individual agreement according to local policy.

Supply of potassium iodide 65mg tablets to adults and children exposed to radioactive iodine, or at risk of exposure

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. It is also your responsibility to ensure that all consultation with patients allows a suitable level of confidentiality.

Note to Authorising Authority: authorised staff should be provided with an individual copy of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to provide the potassium iodide tablets in accordance with this PGD.

Name of approved practitioner _____

Designation/profession _____

Professional registration number _____

Signature _____ Date _____

Where required, name and signature of line manager/ professional lead authorising the above named individual

Name: _____

Signature: _____ Date _____

Signed copy to be returned to _____ NHS Trust/ Board