

PATIENT GROUP DIRECTION (PGD)Administration of Rotarix[®] oral suspension (Rotavirus vaccine, live)

Infants aged 6 to 24 weeks

For the supply of Rotarix[®] oral suspension (*Rotavirus vaccine, live*) by nurses currently registered with the Nursing and Midwifery Council (NMC) to infants aged 6 to 24 weeks

Reference no: *Rotavirus PGD*Version no: *Version final*Valid from: *1st July 2013*Review date: *30th June 2014*Expiry date: *30th June 2015*

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 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 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 condition or situation to which the direction applies.

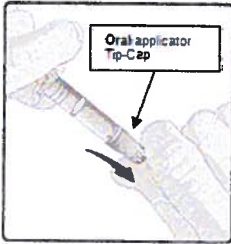

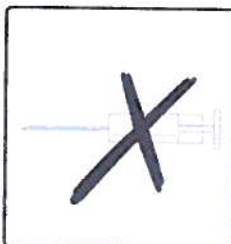
Indication	Rotarix® is indicated for the active immunisation of infants aged 6 to 24 weeks for the prevention of gastro-enteritis due to rotavirus infection, in line with the recommendations given in Chapter 27b of the <i>Immunisation Against Infectious Disease: The Green Book</i> .
Objective of programme	The objective of the rotavirus immunisation programme is to provide two doses of Rotarix® vaccine to infants from six weeks of age and before 24 weeks of age in order to prevent severe gastroenteritis due to rotavirus.
Criteria for inclusion	Infants aged 6 weeks to under 15 weeks of age. The minimum age for the first dose of Rotarix® is 6 weeks 0 days. The maximum age for the first dose is 14 weeks and 6 days.
Criteria for exclusion¹	<p>Infants aged under six weeks Rotarix® should NOT be given to infants under 6 weeks of age.</p> <p>Infants aged 15 weeks to 24 weeks Infants aged 15 weeks and 0 days or older, who have not yet received their first dose, should NOT be started on Rotarix.</p> <p>Infants aged 24 weeks or older Rotarix® vaccine should NOT be given to an infant who is 24 weeks and 0 days of age or older.</p> <p>In addition Rotarix® should NOT be given to:</p> <ul style="list-style-type: none"> • Infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine; • Infants with a confirmed anaphylactic reaction to any component of the vaccine; • Infants with a previous history of intussusception; • Infants with Severe Combined Immunodeficiency Disorder (SCID); • Infants who have an uncorrected (congenital) malformation of the gastrointestinal tract that could predispose them to intussusception; • Infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. <p>Immunosuppression The vaccine contains a live attenuated virus and there is limited evidence of safety and efficacy data in infants with</p>

¹ Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it would be outside the remit of the PGD and another form of authorisation will be required.

	<p>immunosuppression other than SCID, where the vaccine should NOT be offered.</p> <p>In other cases of immunosuppression, the vaccine may be considered – but this is not in the remit of this PGD. In such cases, the infant's General Practitioner (GP) should issue a patient specific direction (PSD) or administer the vaccine themselves. As with all complex cases, it is good practice to involve the infant's clinician in the decision whether to immunise.</p> <p>Temporary Exclusion Administration of Rotarix should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection is not a contra-indication for immunisation.</p> <p>The administration of Rotarix should be postponed in subjects suffering from diarrhoea or vomiting. This is to ensure that the vaccine is not regurgitated, or passed through the intestines too quickly, which could reduce its effectiveness.</p>
Action if excluded	<p>Important - see above regarding age of infant as exclusion criteria where no further action will be required.</p> <p>Seek appropriate advice from a Consultant in Health Protection or the infant's clinician.</p> <p>The risk to the infant of not being immunised must be taken into account.</p> <p>Temporary exclusion In case of postponement due to acute illness, arrange a future date for immunisation (if the infant will still be within the age range recommended above).</p> <p>Document in infant's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP.</p>
Action if patient or carer declines treatment	<p>Advise parent/carers about the protective effects of the vaccine, the risks of infection, disease including potential complications.</p> <p>Document advice given and decision reached.</p> <p>In a GP practice setting, inform or refer to the GP.</p>
Reference to national / local policies or guidelines	<p>Chapter 27b of <i>Immunisation Against Infectious Disease: The Green Book</i>.</p>
Precautions	<p>See sections on Inclusion and Exclusion Criteria and Dose.</p> <p>Very premature infants (born ≤ 28 weeks of gestation) who are in</p>

	hospital should have respiratory monitoring for 48-72 hours when given their first routine immunisations, particularly those with a previous history of respiratory immaturity.
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2. Description of Treatment

Name, strength & formulation of drug	Rotarix® oral suspension (1.5 ml) in pre-filled oral applicator (Rotavirus vaccine, live).
Presentation	See section on Supply.
Storage	Vaccines should be stored in the original packaging at +2°C to +8°C and should be protected from light. All vaccines are sensitive to some extent to heat or cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness will be reduced for vaccines unless they have been stored at the correct temperature. Freezing may cause increased reactogenicity and loss of potency.
Legal status	Prescription Only Medicine (POM).
Black Triangle▼	No.
Unlicensed / off label use	No.
Route / method	<p>Rotarix® vaccine is given orally.</p> <p>Rotavirus vaccines must NOT be injected.</p> <p>Instructions for administration of the vaccine: To administer the vaccine, carefully remove the protective tip-cap from the oral applicator. Seat the child in a reclining position and administer the entire content of the oral applicator orally (i.e. into the child's mouth, towards the inner cheek).</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  <p>1. Remove the protective tip cap from the oral applicator.</p> </div> <div style="text-align: center;">  <p>2. This vaccine is for oral administration only. The child should be seated in a reclining position. Administer orally (into the child's mouth, towards the inner cheek) the entire content of the applicator.</p> </div> <div style="text-align: center;">  <p>3. Do not inject.</p> </div> </div>

	<p>The Summary of Product Characteristics for Rotarix[®] provides further guidance on administration.</p> <p>http://www.medicines.org.uk/emc/medicine/17840/SPC/rotarix</p> <p>Rotavirus vaccine can be given at the same time as, or any time before or after, any of the other vaccines administered as part of the routine childhood immunisation programme between 6 and 15 weeks of age, including BCG vaccine. Ideally Rotavirus vaccine should therefore be given at the scheduled two and three month immunisation visits.</p> <p>If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same or a subsequent immunisation visit. There are no restrictions on an infant's consumption of food or drink before or after immunisation.</p>
Dose	<p>Schedule</p> <ul style="list-style-type: none"> • First dose of 1.5 ml of Rotarix[®] vaccine at two months (approximately eight weeks) of age; • Second dose of 1.5 ml at least four weeks after the first dose <p>Infants who have received their first dose of vaccine before 15 weeks of age, should receive their second dose of Rotarix[®] by 23 weeks and 6 days of age.</p> <p>However, it is preferable that the full course of two doses of Rotarix[®] be completed before 16 weeks of age, allowing at least four weeks between the first and second dose. This is to provide protection before the main burden of disease and to avoid temporal association between immunisation and intussusception. In line with recommendations from WHO, infants older than 15 weeks of age, who have not yet received their first dose of vaccine, should NOT be commenced on Rotarix[®] (see criteria for inclusion).</p> <p>Infants who receive the first dose of Rotarix[®] before 15 weeks of age, should complete the course by 24 weeks of age. If the course is interrupted, it should be resumed but not repeated, provided that the second dose can be given before the 24 week cut-off (see criteria for inclusion).</p>
Frequency of administration	See section on Dose.

Duration of treatment	See section on Dose.
Supply	Rotarix [®] vaccine is supplied as an oral suspension of clear colourless liquid in an oral applicator containing the suspension solution (1.5 ml), with a plunger, stopper and a protective tip cap
Total doses	Maximum two doses
Disposal	Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in an oral applicator, should be disposed of at the end of a session by sealing in a proper, puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2006).
Drug interactions²	None reported.
Identification & management of adverse reactions²	<p>The most common adverse reactions observed after administration of Rotarix[®] vaccine are diarrhoea and irritability. Other reactions uncommonly reported are abdominal pain, flatulence, vomiting, skin inflammation, regurgitation of food, fever and loss of appetite.</p> <p>A detailed list of adverse reactions associated with Rotarix[®] is available in the Summary of Product Characteristics for this vaccine, which is available from the European Medicines Agency website: http://www.medicines.org.uk/emc/medicine/17840/SPC/Rotarix/</p> <p>Intussusception is a naturally-occurring condition where the part of the intestine prolapses, or telescopes, into another part causing an obstruction. Intussusception has a background annual incidence of around 120 cases per 100,000 children aged under one year. The background risk of intussusception in the UK increases with age to a peak at around 5 months. Research from some countries suggests that Rotarix[®] may be associated with a very small increase in the risk of intussusception within seven days of immunisation, by possibly two cases per 100,000 first doses given, and the Rotarix[®] prescribing information includes this as a possible side effect.</p> <p>The benefits of immunisation in preventing the consequences of rotavirus infection outweigh this small potential risk in young children. However, because of this potential risk and to reduce the likelihood of a temporal association with rotavirus immunisation, the first dose of vaccine should not be given after 15 weeks of age.</p>

² Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Patient advice and follow up treatment	When applicable, advise parent/carer when the subsequent dose is due.
Reporting procedure of adverse reactions	<p>As with all vaccines, healthcare professionals and parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk</p> <p>Any serious adverse reaction to the vaccine should be documented in the infant's record.</p> <p>The infant's GP should also be informed.</p>
Advice to patient/carer including written information	<p>Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Inform patient/carer of possible side effects and their management.</p> <p>The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction.</p>
Special considerations and additional information	<p>Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection and access to a telephone.</p> <p>Minor illnesses without fever or systemic upset are NOT valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine.</p>

Records	<p>Record:</p> <ul style="list-style-type: none"> • That valid informed consent was given; • Name of patient, address, date of birth and GP with whom the infant is registered; • Name of member of staff who supplied the vaccine; • Date of supply • Dose and form of vaccine supplied; • Quantity supplied; • Batch number and expiry date; • Advice given; • Advice given if excluded or declines immunisation; • Record how the infant's central record or GP surgery record will be updated;
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	<ul style="list-style-type: none"> • Details of any Adverse Drug Reactions and actions taken; • Record supplied via Patient Group Direction (PGD). <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the infant's GP record AND the personal Child Health record (PCHR) – the <i>Red Book</i>.</p> <p>A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.</p> <p>Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death.</p> <p>Data must be stored in accordance with Caldicott guidance and the Data Protection Act.</p>
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3. Characteristics of Staff


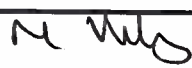
Qualifications required	<p>Nurses currently registered with the Nursing and Midwifery Council (NMC);</p> <p>Other trained and appropriately qualified professionals as detailed in Chapter 5 of <i>Immunisation Against Infectious Disease: The Green Book</i>.</p>
Additional requirements	<ul style="list-style-type: none"> • You must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction (PGD) before working to it; • You must have undertaken appropriate training for working under a PGD for supply of medicines; • You must have undertaken training appropriate to this PGD; • You must be competent to undertake immunisation and to discuss issues related to immunisation; • You must be competent in the recognition and management of anaphylaxis.
Continued training requirements	<ul style="list-style-type: none"> • You must maintain your own level of updating with evidence of Continued Professional Development (CPD); • You should be constantly alert to any subsequent recommendations from the Department of Health and other sources of medicines and vaccine information.

5. ORGANISATIONAL AUTHORISATIONS

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

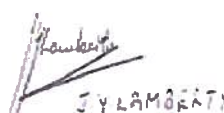

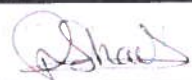
It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

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

Approved by:	Name	Signature	Date
Local Clinical Governance Committee e.g. DTC/MMT SMT 30/8/13	Dr DAVID BLAIR		29 th August 2013
Additional signatories according to local policy e.g. independent contractor providers.	M KITCHING		29/8/13

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.

4. PGD Development

Developed & produced by:	Name	Signature	Date
Senior Pharmacist	Jackie Lamberty	 J Y LAMBERTY	4 th June 2013
Doctor (Lead Author)	Dr Penelope Toff		4 th June 2013
Primary Care Practice nurse	Priti Shah		7 th June 2013

Acknowledgements

Name	Designation
Dr Saurabh Gupta	Locum Consultant Epidemiologist, PHE
Dr Mary Ramsay	Head of Immunisation, PHE

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

Practitioner

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct

Signed.....Date.....
..

Name
(Print).....

Designation.....
..

Authorising Manager

Manager to give authorisation on behalf of xxx (insert name of organisation) for the named Health Care Professional who has signed the PGD

Signed..... Date.....

Name (Print).....

Designation.....

Note to Authorising Manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the PGD

