

Rotavirus (live oral vaccine)

GG&C PGD ref no: 2017/1427

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition

Indication:

Active immunisation against rotavirus.

Inclusion criteria:

- As part of the routine childhood immunisation schedule <http://www.hps.scot.nhs.uk/immvax/index.aspx>
- Parent/carer consent
- Infants from 6 weeks to 24 weeks.

Exclusion criteria:

- Over 24 weeks of age (i.e. older than 23 weeks and 6 days).
- Infants who have not received their first dose before 15 weeks of age (i.e. older than 14 weeks and 6 days).
- Severe Combined Immunodeficiency (SCID) disorder
- Confirmed anaphylactic reaction to a previous dose of rotavirus vaccine.
- Confirmed anaphylactic reaction to any component of the vaccine. Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of vaccine components.
- Previous history of intussusception.
- Congenital malformation of the gastrointestinal tract that could predispose individual to intussusception.
- Rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- Infants whose mothers have received immunomodulating biologics (such as monoclonal antibodies or receptor antagonists which interfere with the immune system e.g. anti-TNF agents) in pregnancy and breast feeding
- Immunosuppression.
- Acute severe febrile illness – consider postponing immunisation until patient has fully recovered.
- Acute diarrhoea or vomiting - consider postponing immunisation until patient has fully recovered.
- Evolving neurological condition, immunisation should be deferred until resolved or stabilised

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<p>Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:</p>	<ul style="list-style-type: none"> • Rotarix® can be given at the same time as the other vaccines administered as part of the childhood immunisation programme including all currently used live vaccines and BCG. • If a child born very prematurely (< 28 weeks) has had a reaction to a first immunisation administered in hospital, they should return to hospital for their second immunisation
<p>Action if patient declines or is excluded:</p>	<p>Refer to appropriate clinician e.g. GP, Travel Health Consultant, Sexual Health, GUM or ID Consultant. If declined advise regarding protective effect of immunisation and potential disease complications. Document advice given and refer to appropriate clinician.</p>
<p>Referral arrangements for further advice / cautions:</p>	<p>As above</p>

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Drug Details	
Name, form & strength of medicine:	Rotavirus vaccine, Live (Rotarix®). Oral suspension in a prefilled oral applicator or tube
Route/Method of administration:	Oral use only. Rotarix® must not be injected.
Dosage (include maximum dose if appropriate):	The course consists of two 1.5ml doses with an interval of at least four weeks between the doses. The recommended age for immunisation is the first dose at two months of age (approximately eight weeks) followed by the second dose at least four weeks after the first dose. Infants older than 15 weeks of age (i.e. older than 14 weeks and 6 days), who have not received a first dose of Rotarix®, should not be offered Rotarix®. Infants who receive the first dose before week 15 should complete the course by 24 weeks (i.e. by 23 weeks and 6 days). If the course is interrupted it should be resumed but not repeated, in line with the restrictions on timings above. If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit.
Frequency:	As above
Duration of treatment:	n/a
Maximum or minimum treatment period:	n/a
Quantity to supply/administer:	As above
▼ Additional Monitoring:*	No
Supply, Administer or Both:	Administer only
Legal Category:	POM
Is the use outwith the SPC:**	Yes. SPC does not give dose for baby born at 27 weeks but Green Book advises all premature babies
Storage requirements:	Store between 2°C-8°C in locked storage. NHS GG&C Vaccine Ordering, Storage and Handling Guidelines should be observed http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Vaccine%20Ordering%20Storage%20and%20Handling%20Guideline.pdf Vaccine storage history e.g. temperature charts must be checked and deemed satisfactory before administration to patient.

* The black triangle symbol has now been replaced by European “additional monitoring (▼)”

** Summary of Product Characteristics

Date Approved: 26 January 2017

Version: 5

Review Date: July 2018

Expiry Date: January 2019

Template Version: 2017

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<p>Warnings including possible adverse reactions and management of these:</p>	<p>Please refer to current BNF, eBNF http://emc.medicines.org.uk/ or SPC at http://emc.medicines.org.uk/ for full details</p> <p>Use the Yellow Card System to report adverse drug reactions directly to the CMS. Yellow Cards and guidance on their use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/</p>
<p>Advice to patient/carer including written information provided:</p>	<p>Explain treatment and course of action.</p> <p>Further Information available to patients at www.immunisationscotland.org.uk Give patient a copy of relevant patient information leaflet, if appropriate.</p> <p>If condition worsens or symptoms persist then seek further medical advice</p> <p>Carers of a recently vaccinated baby should be advised of the need to wash their hands after changing the babies nappies</p>
<p>Monitoring (if applicable):</p>	<p>NA</p>
<p>Follow up:</p>	<p>See advice to patient/carer</p>

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Staff Characteristics

Professional qualifications:	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.
Specialist competencies or qualifications:	Has undertaken appropriate training and competence to undertake immunisation including recognition and treatment of anaphylaxis Has undertaken appropriate training for working under PGDs for the supply and administration of medicines
Continuing education & training:	All health care professionals working under the direction will be expected to maintain their competence as specified in hospital, local and national policies e.g. Nursing & Midwifery Council guidelines. The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development in all aspects of immunisation including recognition and treatment of anaphylaxis.

Referral Arrangements and Audit Trail

Referral arrangements	GP if required
Records/audit trail:	<p>Patient's name, address, date of birth and consent given; Contact details of GP (if registered); Dose and form administered (batch details and expiry date); Advice given to patient (including side effects); Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment; Details of any adverse drug reaction and actions taken including documentation in the patient's medical record; Referral arrangements (including self-care) Administration must be recorded on the SIRS sheet, GP, Travel Health clinic or Primary Care clinic record as appropriate. Childhood Immunisations should be recorded on the parent held record if possible. In 'paper free' GP surgeries signature of the nurse who administered the vaccination should be made on the SIRS sheet when appropriate. A copy of this should be retained for reference.</p>

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**References/
Resources
and
comments:**


Notes:
SPC – Summary of Product Characteristics <http://emc.medicines.org.uk/>
BNF – British National Formulary <http://emc.medicines.org.uk/>
NMC (2008) Standards for Medicines Management
NMC (2015) The NMC Code of Professional Conduct: standards for conduct, performance and ethics <http://www.nmc-uk.org/>
NHS GG&C Immunisation Best Practice Guideline
<http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Immunisation%20Best%20Practice%20Guideline.pdf>
NHS GG&C Vaccine Ordering Storage and Handling Guidelines
<http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Vaccine%20Ordering%20Storage%20and%20Handling%20Guideline.pdf>
Immunisation against Infectious Diseases (2006). DOH (green book) always refer to on-line version
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917
NHS HealthScotland website
<http://www.healthscotland.com/topics/health/immunisation/index.aspx>
Health Protection Scotland Immunisation and Vaccine Preventable Diseases website <http://www.hps.scot.nhs.uk/immvax/guidelines.aspx>
Immunisation Scotland www.immunisationscotland.org.uk
Training material available at:
<http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/rotavirus.aspx>
Revised recommendations for the administration of more than one live vaccine , Public Health England accessed at
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/353085/11092014_PHE_live_vaccine_interval_v3.pdf

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This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at PPSU, 2nd Floor, Main Building, West Glasgow ACH. The PGD must be easily accessible in the clinical setting.

Organisation: NHS Greater Glasgow & Clyde


Professionals drawing up PGD/Authors


Professionals drawing up PGD/Authors	
	Designation and Contact Details
<p>Name: Dr Syed Ahmed</p>  <p>Signature: _____ Date: 30/11/2017</p>	<p>Designation: Consultant in Public Health Medicine Public Health Protection Unit Westhouse, NHS GG&C</p> <p>E-mail address: syed.ahmed@ggc.scot.nhs.uk</p>
<p>Name: *Val Reilly</p>  <p>Signature: _____ Date: 30/11/2017</p>	<p>Designation: Public Health Pharmacist Pharmaceutical Public Health Westhouse, NHS GG&C</p> <p>E-mail address: val.reilly@ggc.scot.nhs.uk</p>
<p>Name: Hilda Crookshanks</p>  <p>Signature: _____ Date: 21/12/2017</p>	<p>Designation: Health Protection Nurse Specialist</p> <p>E-mail address: hilda.crookshanks@ggc.scot.nhs.uk</p>

* Lead Author

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AUTHORISATION:

NHSGG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	Signature:	Date:
Dr Craig Harrow		30/11/2017

NHSGG&C PGD Sub-Committee of ADTC		
NMP Professional Lead in BLOCK CAPITALS	Signature:	Date:
Gavin Gorman		30/11/2017

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	Signature:	Date:
Maria Tracey		30/11/2017

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Local Authorisation:

Service Area for which PGD is applicable:

I authorise the supply/administer medicines in accordance with this PGD to patients cared for in this service area.

Lead Clinician for the service area (Doctor)

Name:	Signature:	Designation:	Date:

E-Mail contact address:

I agree that only fully competent, qualified and trained professionals are authorised to operate under the PGD. Records of nominated individuals will be kept for audit purposes.

Name (Lead Professional):	Signature:	Designation:	Date:

E-Mail contact address:

Description of Audit arrangements:

Frequency of checks: (Generally annually)	Names of auditor(s):

**PGDs DO 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.**

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

I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	Signature	Date

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Short Patient Group Direction Audit Form
Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

Name and post of Designated Lead person within each practice/clinic base:			
Location/Clinic Base:	Date of audit:		
Tick as appropriate. If 'no', state action required	Y	N	Action
Is the PGD or PGDs utilised within the clinical area?			
Has the PGD or PGDs been reviewed within the 2 year limit?			
Do the managers listed on the PGD or PGDs hold a current list of authorised staff?			
Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?			
Do all staff meet the training requirements identified within the PGD?			
Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?			
Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?			
Where the medicine requires refrigeration. (Delete if not required).			
Is there a designated person responsible for ensuring that the cold chain is maintained?			
Is there a record that the fridge temperature has been monitored to required levels?			
If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response).			

Name:	Date of audit:
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Keep copies of completed audits alongside your PGD for local reference. Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.