Approved by Quality & Patient Safety Committee
19 February 2015

ROTARIX VACCINE

POISON SCHEDULE S4

DESCRIPTION

Live attenuated human rotavirus vaccine.

USE

Protective immunity against rotavirus gastroenteritis in infant population. The introduction of Rotavirus vaccines has decreased rotavirus-associated hospitalizations for children by 70% since 2007. (www.tga/gov/au/sfety/alerts-medicine-rotavirus-110225.htm)

PRESENTATION

Clear colourless ORAL liquid suspension; ready to use with no reconstitution or dilution required.

DOSE

1. The vaccine course consists of 2 doses.
2. Each dose is 1.5ml.
3. The first dose is to be given on or after discharge from the Newborn Care Centre, between 6 weeks and 14 weeks 6 days of chronological age.
4. The second dose should be given by the infant's general practitioner a minimum of 4 weeks after first dose. Not to be given after 24 weeks of age as its safety has not been assessed in older children.

ADMINISTRATION *Oral administration only!*

1. NOT TO BE INJECTED UNDER ANY CIRCUMSTANCES.
2. Administration orally via applicator to inside of cheek with infant in reclined position.
3. Rotarix should be administered only at discharge, or after discharge from the Newborn Care Centre, as viral antigen particles are found in 50% of stools after the first dose, and there is a potential risk of transmission to unvaccinated contacts.

STORAGE

1. Refrigerate at 2 to 8 °C. Do not freeze.
2. Store in original packaging to protect from light.
3. Discard unused portion.

ADVERSE EFFECTS

1. Diarrhoea, appetite loss, irritability and fever have been reported but these symptoms were not increased in treatment versus control groups in large placebo controlled trials.
2. Possible risk of intussusception in preterm infants (www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/immunise-rotavirus).

CONTRAINDICATIONS

1. Chronic gastrointestinal disease including uncorrected congenital gastrointestinal malformations.
2. Acute severe febrile illness.

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ROTARIX VACCINE cont'd

PRECAUTIONS

1. Rotarix administration should be postponed in infants suffering from diarrhoea or vomiting.
2. Rotarix should be administered with caution to infants with close contacts who are immunodeficient.
3. Contacts of vaccines should be advised to wash hands after changing nappies.
4. Vaccination of infants born to immunocompromised women (due to immunosuppressive medication or an underlying immune deficiency condition) should only be undertaken after consultation with the senior medical officer

COMPATIBILITY

Rotarix may be co-administered with DTPa, Hib, IPV, HBV, pneumocccal conjugate vaccine and meningococcal serogroup C.

INCOMPATIBILITY

An interval of 2 weeks between Rotarix and oral polio vaccine is advised.

REFERENCE

1. MIMS Full Prescribing Information via CIAP October 2014
2. NHMRC. The Australian Immunisation Handbook 10th Edition 2010
3. Advisory Committee on Immunisation Practices to the Centres for Disease Control and Prevention.
4. GlaxoSmithKline Australia Data on File: Study 106481 (Rota 054) 2008, and Study 444563 (Rota 023) 2004.

Risk rating: Low. Review in 2020

REVISION & APPROVAL HISTORY

Reviewed and endorsed Therapeutic & Drug Utilisation Committee 10/2/15
Approved Quality & Patient Safety Committee 18/8/11
Reviewed & endorsed Therapeutic & Drug Utilisation Committee 16/8/11
Approved Quality & Patient Safety Committee 15/10/09

FOR REVIEW : FEBRUARY 2020