

ROTAVIRUS VACCINE (Rotarix®)

Trade Name	Rotarix®. GlaxoSmithKline NZ Limited
Class	Live attenuated oral vaccine
Mechanism of Action	Rotarix® induces development of antibodies against G1P(8) and other nonG serotypes of human rotavirus. Exact mechanism unknown. ²
Indications	Protection against rotavirus infection. Rotarix® is intended for administration in the first 6 months of life, it should not be administered to children older than 24 weeks of age.
Contraindications	Known history of allergy to Rotarix® or any of its constituents. Infants with severe combined immune-deficiency syndrome. Infants who have suffered from intussusception. Rotavirus vaccines should not be given to infants with any chronic gastrointestinal disease including uncorrected congenital malformation of the GI tract. Current gastroenteritis symptoms or fever more than 38 degrees - administration of Rotarix® should be postponed in infants suffering from diarrhoea or vomiting
Supplied As	Rotarix® is supplied as 1.5mL of clear oral suspension in a pre-filled oral applicator with a plunger stopper. Each 1.5 mL dose of the vaccine contains not less than 10 ^{6.0} CCID ₅₀ (cell culture infectious dose 50%) of the RIX 4414 strain of human rotavirus. The vaccine also contains sucrose, di-sodium adipate, Dulbecco's Modified Eagle Medium and sterile water. Rotarix® is an oral vaccine and must <u>NOT</u> be injected.
Dilution	N/A
Dosage	A 1.5 mL single, oral dose is given at 6 weeks and 3 months chronological age . The only exceptions to giving the vaccine at the chronological age with the other scheduled vaccinations would be if the baby was unable to take the volume orally or if they were significantly unwell/unstable. To be discussed with the medical team when vaccinations are planned. If the vaccine cannot be given at 6 weeks then plan to administer the first dose with the 3 month vaccinations or discharge, whichever is earliest. Note the first dose must be given before 15 weeks of age (day 104) and the course of 2 vaccinations must be completed before the child is 25 weeks (day 174)
Guardrail	N/A
Interval	There should be a minimum of 4 weeks between doses.

Administration	<p>Oral</p> <p>Administer into the inner cheek and avoid the tip of the tongue area to ensure that the fluid is swallowed.</p> <p>If a dose is regurgitated or vomited do not repeat the dose.</p> <p>If the baby is unable to swallow safely by day 104 then the rotavirus vaccine may be given by nasogastric tube</p> <p>Rotavirus vaccine <u>must not</u> be given to any baby who has a gastrointestinal condition that puts them at risk of intussusception</p>
Compatible With	<p>Rotarix® may be given at the same time as other routine childhood vaccinations. Prevenar 13®, Synflorix®, Infanrix –hexa.®</p> <p>Rotarix® may also be given at the same time as other live attenuated vaccines eg BCG.</p> <p>If administration of oral polio vaccine is required then an interval of two weeks between Rotarix® and polio vaccine is recommended.</p> <p>No need to withhold Rotarix® after receiving blood products, or after cardiac bypass</p> <p>See Neonatal Handbook regarding Rotarix® after steroid courses.</p>
Incompatible With	N/A
Interactions	No known medicine interactions ² .
Monitoring	Ensure use of universal infection control precautions when handling infants who have recently received rotavirus vaccination to avoid any risk of contamination or faecal-oral spread. Shedding occurs in 13% of cases for up to 28 days after the first dose.
Stability	Single Use, discard immediately after use
Storage	<p>Rotarix® should be protected from light and stored in the fridge at 2- 8 °C. Do not freeze.</p> <p>To protect the “cold chain” vaccines are no longer kept as stock in ward fridges and should be ordered from pharmacy as required. They will be delivered in a chilly bin and if not used within 60 minutes need to be taken to the Delivery Suite fridge, taken out of the chilly bin and put into the fridge until required.</p>
Adverse Reactions	Fever, abdominal pain, diarrhoea and vomiting, flatulence, constipation, irritability, loss of appetite, cough/runny nose, dermatitis, rare cases of intussusception ⁶ .
Metabolism	N/A, Excreted in faeces.
Comments	<ul style="list-style-type: none"> In Australia immunisation reduced the rate of hospitalisation for rotavirus infection by 70%.

	<ul style="list-style-type: none"> • It is expected that the vaccination will give protection against rotavirus for 3 years following the last dose.^{3,4} • The reason for the recommended dosing schedule is because this is the patient group that the vaccine has been tested in.^{2,3,4,6}
References	<ol style="list-style-type: none"> 1. www.nzfc.org.nz 2. http://medsafe.govt.nz/profs/Datasheet/r/Rotarixliquidvac.pdf 3. Batty K. 2017 updates to the New Zealand National Immunisation Schedule. Research Review Educational series http://www.medsafe.govt.nz/Consumers/CMI/r/Rotarix.pdf 4. http://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/new-zealand-immunisation-schedule 5. Starship Immunisation guideline 6. http://www.medsafe.govt.nz/Consumers/CMI/r/Rotarix.pdf 7. The Immunisation Advisory Centre: Quick answers to frequent rotavirus vaccine questions. www.immune.org.nz
Updated By	<p>A Lynn, B Robertshawe June 2017 A Lynn, B Robertshawe January 2022</p>