Rotavirus vaccine (Rotarix)

Newborn use only

2025

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<tr><td>Alert</td><td>ORAL ADMINISTRATION ONLY
The first dose of rotavirus vaccine should be given to infants between 6 and 14 weeks chronological age (prior to turning 15 weeks chronological age) and the second dose by 24 weeks of age (prior to turning 25 weeks of age).
The interval between dose 1 and 2 should not be less than 4 weeks.
In Australia and New Zealand, regular look up for any online updates by the Immunisation Handbook is recommended.</td></tr>
<tr><td>Indication</td><td>Primary immunisation against rotavirus gastroenteritis.</td></tr>
<tr><td>Action</td><td>Live attenuated human rotavirus vaccine that induces protective immunity against the G1P (8) strain and some other non-G1 prevalent strains of rotavirus.</td></tr>
<tr><td>Drug Type</td><td>Vaccine.</td></tr>
<tr><td>Trade Name</td><td>Rotarix</td></tr>
<tr><td>Presentation</td><td>1.5 mL oral suspension in an oral applicator with plunger stopper or in a squeezable tube.</td></tr>
<tr><td>Dose</td><td>1.5 mL orally.
Primary schedule: 2-dose course administered with 2- and 4-month immunisations i.e., dose 1 can be administered at 6 to 14 weeks of age and dose 2 can be administered at 14 to 24 weeks of age.
NOTE: Dosage interval between first and second doses must be greater than 4 weeks.

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<tr><th>Schedule</th><th>Age limit for first dose</th><th>Age limit for second dose</th><th>Minimum interval between doses</th></tr>
<tr><td>2 oral doses (1.5 mL/dose)</td><td>6–14 weeks</td><td>14–24 weeks</td><td>4 weeks</td></tr>
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NOTE: If most of the oral rotavirus vaccine has been regurgitated or vomited within minutes of administration, a single repeat dose can be administered during the same immunisation encounter. If an infant regurgitates or vomits only a small part of a vaccine dose, it is not necessary to repeat the dose.

Catch-up schedule: If an infant has NOT had a dose of any rotavirus vaccine AND is ≥ 15 weeks then that infant is NOT ELIGIBLE to commence any rotavirus vaccination dose.[1]

Preterm infants: Vaccine is administered at a chronologic age (without correction for prematurity) similar to term infants, if the infant is clinically stable.[1]

Hospitalised infants: If standard infection control precautions are maintained and the infant is medically stable, vaccination should not be delayed, particularly if the delay would result in an infant being beyond the upper age limit for vaccination.[1]

Systemic corticosteroid therapy: Rotavirus vaccine is not contraindicated in neonates on inhaled or systemic corticosteroids if they are otherwise medically stable. [1]

Exposure to anti-CD20 therapy in utero: Rotarix should be withheld in infants whose mothers were taking anti-CD20 therapy (including rituximab) during pregnancy. Rotarix can be given to infants whose mothers were taking other biologic immunosuppressants during pregnancy.[1]

Other live vaccines: Rotavirus vaccine can be given at any time before or after the routine infant immunisations and at any time before or after BCG vaccine. The recommendation for administering live vaccines either at the same time or after an interval of four weeks only applies to injectable live viral vaccines and, therefore, not to BCG or to the oral rotavirus vaccines.[2]</td></tr>
<tr><td>Dose adjustment</td><td></td></tr>
<tr><td>Maximum Dose</td><td>Limited data on the safety of administering higher than the recommended dose.</td></tr>
<tr><td>Route</td><td>Oral or via gastric tube</td></tr>
<tr><td>Preparation</td><td>The vaccine is ready to use; no reconstitution or dilution is required.</td></tr>
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Administration	The vaccine is presented as a clear and colourless liquid. It should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, the vaccine is not suitable for use. Oral: Administer entire applicator or dosing tube content on inside of cheek with child in reclining position. Gastric tube: For infants who can't take the vaccine orally, it can be administered via a gastric tube; flush with air to clear the tube. Can be given with or without feeds. Record details of vaccination in patient's Personal Health Record ('Blue Book'), Australian Immunisation Register and medication chart. Other vaccines can be given at the same time (refer to Drug interactions section). Discard the empty oral applicator and tip cap according to local regulations.
Monitoring	Symptoms suggestive of intussusception such as severe abdominal pain or distress, persistent vomiting, bloody stools, palpable abdominal mass, abdominal bloating and/or high fever. Parents should be advised to seek medical advice promptly where these symptoms are evident.
Contraindications	Anaphylaxis following a previous dose of rotavirus vaccine. Anaphylaxis following any vaccine component. Previous history of intussusception or a congenital abnormality that may predispose to intussusception. Fatal intussusception after the second dose has been reported in infants with a history of intussusception after the first dose. Severe Immunocompromised status including maternal anti-CD20 therapy during pregnancy Severe Combined Immunodeficiency (SCID). Do not administer to (i) infants older than 24 weeks of age as safety has not been demonstrated, particularly in relation to risk of intussusception, (ii) infants with malformation of the gastrointestinal tract that could predispose them to intussusception, (iii) hereditary fructose intolerance, glucose/galactose malabsorption or sucrase-isomaltase insufficiency. If infant is > 14 weeks and inadvertently receives 1st dose of rotavirus vaccine, reassure parents and discuss minimally increased risk of intussusception. Provide information on symptoms/signs of intussusception. If infant is < 25 weeks (upper limit for dose 2 of rotavirus vaccine), and minimum interval of 4 weeks between vaccine doses can be achieved, give a second dose of rotavirus vaccine
Precautions	Use with caution in infants with underlying conditions predisposing to severe rotavirus gastroenteritis (including metabolic disorders or chronic gastrointestinal disease e.g., Hirschsprung's disease, malabsorption syndrome or short gut syndrome). Severe acute gastroenteritis (e.g. necrotising enterocolitis) Significant acute illness or temperature greater than 38°C (postpone vaccine until neonatologist approves). Use with caution in immunosuppressed infants (the theoretical risk for vaccine virus-associated disease is considered likely to be less than their risk from being exposed to disease from natural infection). Infants with a moderate to severe illness should be vaccinated after recovery. In addition to the factors mentioned above, this avoids superimposing potential adverse events related to vaccination on any concurrent illness. Minor infections, without fever or systemic upset, are not reasons to postpone vaccination. Fever secondary to environmental factors is not a reason to postpone vaccination. Viral shedding in stools, particularly after the first dose, could pose a risk of transmission of virus to immunocompromised close contacts. Good hygiene practices and contact precautions MUST be observed at ALL times (i.e. washing hands regularly, especially after changing nappies).
Drug Interactions	Co-administration studies have demonstrated that rotavirus vaccine can be given concomitantly with any of the following vaccines: Diphtheria tetanus acellular pertussis vaccine (DTPa), Haemophilus influenzae type b vaccine (Hib), inactivated polio vaccine (IPV), hepatitis B vaccine (HBV), hexavalent vaccines DTPa-HBV-IPV/Hib, pneumococcal conjugate vaccine and meningococcal serogroup C conjugate vaccine. The studies demonstrated that the immune responses and the safety profiles of the administered vaccines were unaffected.[1]

Adverse Reactions	Diarrhoea, vomiting and hematochezia. Intussusception—inform parents of the rare risk of intussusception and how to be alert for signs and symptoms. Irritability, flatulence, abdominal pain, dermatitis, Idiopathic thrombocytopenic purpura, bronchopneumonia, Kawasaki disease, hypotonic-hyporesponsive episode have also been reported after vaccination. Any suspected vaccine related adverse reactions should be reported to Therapeutic Goods Authority.
Overdose	AUSTRALIA: Contact the Poisons Information Centre on 13 11 26 for information on the management of overdose NEW ZEALAND: Contact the National Poisons Centre on 0800 764 766 for information on the management of overdose.
Compatibility	Other vaccines can be given concomitantly.
Incompatibility	No information.
Stability	
Storage	Store between 2 and 8°C. Do NOT freeze as this reduces potency. Protect from light. Storage above or below the recommended temperature may decrease potency.
Excipients	sucrose, disodium adipate, Dulbecco's Modified Eagle Medium and sterile water
Special Comments	RotaTeq and interchangeability of vaccine: As of July 2017, RotaTeq (pentavalent human-bovine reassortant rotavirus vaccine) is not used in Australia, but it is available globally. RotaTeq is given as a 3-dose course. Upper age limit for RotaTeq is prior to 33 weeks of age. An infant might have received 1 or 2 doses of RotaTeq overseas prior to arrival in Australia. Where possible the completion of the course of rotavirus vaccine should be with the same vaccine from the same manufacturer. If either dose 1 or dose 2 of the rotavirus vaccine is given as RotaTeq (pentavalent human-bovine reassortant rotavirus vaccine) a third dose of either rotavirus vaccine should be given, provided the upper age limit and inter-vaccine interval are observed.
Evidence	Both rotavirus vaccines have similar efficacy (around 70%) against rotavirus gastroenteritis. The efficacy against severe rotavirus gastroenteritis is higher and ranged from 85% to 100% in clinical trials in many different countries.[1] Preterm infants: Rotavirus vaccine appears safe and equally immunogenic in preterm infants compared to term infants. Vaccine is administered at a chronologic age (without correction for prematurity) similar to term infants, if the infant is clinically stable.[1-7] Hospitalised infants: If standard infection control precautions are maintained, administration of rotavirus vaccine to hospitalised infants, including hospitalised preterm infants, would be expected to carry a low risk for transmission of vaccine viruses. Furthermore, the rotavirus vaccine is highly attenuated and does not revert to a high virulence strain. Provided that the infant is medically stable, vaccination should not be delayed, particularly if the delay would result in an infant being beyond the upper age limit for vaccination. If a recently vaccinated infant is hospitalised for any reason, no precautions other than routine standard precautions need be taken to prevent the spread of vaccine virus in the hospital setting.[1,2] Vaccine recipients may have a 1–3% higher risk of developing diarrhoea or vomiting in the week after vaccine administration. The incidence of fever, irritability and other adverse events was similar in both vaccine and placebo recipients in clinical trials.[1,7-9] Vomiting and diarrhoea have not been noted as important adverse events in post-marketing surveillance of rotavirus vaccines. The increased risk of intussusception after rotavirus vaccination is estimated at approximately 6 additional cases of intussusception among every 100,000 infants vaccinated, or 14 additional cases per year in Australia. The overall benefits of preventing gastroenteritis from rotavirus are much greater than the small risk of intussusception.[1] Fatal intussusception after the second dose has been reported in infants with a history of intussusception after the first dose.[1]

	Case reports indicate prolonged vaccine virus-associated gastrointestinal disease after rotavirus vaccination in infants with Severe Combined Immunodeficiency (SCID). As these infants are unlikely to generate a protective immune response to the vaccine and because of the potential harm, rotavirus vaccines are contraindicated for infants with SCID.[1]
Practice points	
References	1. Australian Immunisation Handbook, Australian Government Department of Health and Aged Care. Accessed on 25/05/2025. 2. Greenbook. United Kingdom Immunisation schedule. Immunisation against infectious disease. Update. Rotavirus. Chapter 27b. Accessed on 25 January 2018. 3. Armstrong C. AAP updates on guidelines on rotavirus vaccination. Am Fam Physician 2010;81(4):552-553 4. Product information: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-06401-3 Accessed 08/05/2025. 5. Pereira P, Vetter V, Standaert B, Benninghoff B. Fifteen years of experience with the oral live-attenuated human rotavirus vaccine: reflections on lessons learned. Expert Rev Vaccines. 2020 Aug;19(8):755-769. 6. Fathima P, Jones MA, Moore HC, et al. Impact of Rotavirus Vaccines on Gastroenteritis Hospitalizations in Western Australia: A Time-series Analysis. J Epidemiol. 2021 Aug 5;31(8):480-486. 7. Costantino C, Conforto A, Bonaccorso N, et al. Safety of Rotavirus Vaccination in Preterm Infants Admitted in Neonatal Intensive Care Units in Sicily, Italy: A Multicenter Observational Study. Vaccines (Basel). 2023 Mar 23;11(4):718. 8. Van Dongen JAP, Rouers EDM, Schuurman R, et al. Rotavirus Vaccine Safety and Effectiveness in Infants with High-Risk Medical Conditions. Pediatrics. 2021 Dec 1;148(6): e2021051901. 9. Wu Z, Li Q, Liu Y, L H, Mo Z, et al. Efficacy, safety and immunogenicity of hexavalent rotavirus vaccine in Chinese infants. Virol Sin. 2022 Oct;37(5):724-730.

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