South Australian Neonatal Medication Guidelines

Rotavirus vaccine

Rotarix® vaccine

Note:

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

Dose and Indications

Primary immunisation against rotavirus gastroenteritis

Oral

1.5mL (Rotarix®) at 6 weeks and 4 months of age

Note: The first dose should be given between 6 to 14 weeks of age (before turning 15 weeks or 105 days of age) and the second dose administered between 10 to 24 weeks, with at least a 4 week interval between the first and second dose. The course should be completed before the end of the 24th week of age.

Provided they are medically stable and there are no contraindications to vaccination, preterm infants should receive vaccines according to the recommended schedule at their chronological age.

The attending clinician should assess medical stability in extremely preterm infants born <28 weeks gestation before vaccination, with reference to Neonatal Unit policy

Preparation and Administration

Oral

FOR ORAL USE ONLY, NOT FOR INJECTION

Rotarix® is a live attenuated vaccine, available in a tube containing 1.5mL suspension.

Squeeze the entire contents of a tube on the inside of the cheek with the child in a reclined position.

If most of the vaccine dose is regurgitated or vomited within minutes of administration, a single replacement dose may be given. If the infant regurgitates or vomits only a small part of the vaccine dose, it is not necessary to repeat the dose.

Record the vaccination in the patient's My Health and Development Record (blue book) and

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Australian Immunisation Register (AIR).

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.

Adverse Effects

Common

Diarrhoea, vomiting

Rare

Intussusception, anaphylaxis

Monitoring

- Observe for 15 minutes after vaccination for immediate adverse effects
- Monitoring for apnoea or bradycardia in premature infants for up to 48 hours should be considered for very preterm infants (born ≤ 28 weeks gestation)

Practice Points

- Vaccination is contraindicated in infants with a congenital abnormality that may predispose to intussusception, a history of intussusception, a history of Severe Combined Immunodeficiency Disease (SCID), anaphylaxis following a previous dose of rotavirus vaccine or anaphylaxis following any vaccine component
- Infants born to mothers who received immunosuppressive biological therapy (i.e., golimumab, infliximab) during pregnancy should not receive any live vaccine until 6 months of age. As it is not recommended to give rotavirus vaccines after 24 weeks of age, these infants are not eligible for vaccination with rotavirus
- Notify senior medical staff of any serious, uncommon or unexpected adverse events possibly related to immunisation, if appropriate report to the South Australian Vaccine Safety Surveillance System (SAVSS) and document as per local procedure
- Administration should be postponed in infants who are medically unstable or suffering from a febrile illness (fever greater than 38.5^{o}C)
- Infants with moderate to severe acute gastroenteritis should delay vaccination until they have recovered. The vaccine can be given to infants with mild gastroenteritis
- Viral shedding can occur post administration, particularly after the first dose. Good hygiene practices and contact precautions must be observed

Document Ownership & History

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