West of Scotland ORAL/ OTHER ROUTE Drug Monographs

Rotavirus Oral Vaccine

FORM Oral suspension in prefilled applicator

INDICATION Primary Immunisation (See WoS Immunisation Guideline for full details of

immunisation programme)

DOSE RANGE

AGE	DOSE	FREQUENCY	ROUTE
6 – 24 weeks	1.5ml	ONCE only (repeat as per Immunisation policy)	Oral

METHOD OF ADMINISTRATION

Rotarix is for **oral** use only, without mixing with any other vaccines or solutions. It MUST NOT be injected

Rotarix should be administered using the applicator provided. The full dose (1.5 ml) should be given into the mouth towards the cheek. If the dose is spat out or vomited an additional dose may be used immediately after the failed dose.

In exceptional circumstances where there is a contra-indication to use of the oral route e.g. absence of gag reflex, Rotarix may be administered via a naso-gastric tube

CAUTIONS, CONTRA-INDICATIONS AND SIDE EFFECTS

See WoS Immunisation Guidelines for more information on cautions and contraindications. See Summary of Product Characteristics and most recent edition of BNF for Children (links below)

Rotarix is a live vaccine and is contraindicated

- in babies with severe combined immune deficiency (SCID).
- In babies with a history of intussusception or who have a malformation of the GI tract which would predispose them to intussusception.
- Babies whose mothers are on medicines a=such as anti-TNF treatment where the baby will be immunosuppresed for a period following cessation of treatment in the mother

Healthcare professionals should follow-up on any symptoms indicative of intussusception (severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever). Parents/guardians should be advised to promptly report such symptoms

FURTHER INFORMATION

If there are any contraindications to rotavirus vaccination at the normal vaccination age the doses may be given at a later date. However, due to a small risk of intussusception when the rotavirus vaccination is administered at later ages the vaccine doses must be given by the following **chronological** ages.

- The first dose should be given ideally by 12 weeks of age and must not be given if the baby is 15 weeks of age or older (more than 14weeks and 6 days)
- The second dose should be given ideally by 16 weeks of age with a minimum interval of 4 weeks and must not be given if the baby is 24 weeks of age or older (more than 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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Rotarix is a live vaccine, although highly attenuated. The vaccine virus is excreted in the faeces for 2-3 weeks after administration. If transmitted

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to an immuno-compromised contact the virus could result in minor gastrointestinal symptoms. Normal hygiene precautions should be used

to prevent transmission.

STORAGE Store in the fridge. Protect from light

LICENSED STATUS Licensed use

LINKS BNF for Children: / Electronic Medicines Compendium

APPLICABLE POLICIES West of Scotland Neonatal Guidelines:

Consult local policy if applicable

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Dose may vary depending on indication, age, renal function, hepatic function, and concomitant medications.

This monograph should be used in conjunction with the package insert, BNF for Children, and Summary of Product Characteristics. For further advice contact your clinical pharmacist or pharmacy department.

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