Prescribing Information: See Summary of Product Characteristics:

ROTARIX® Live attenuated rotavirus vaccine (oral).

Composition: Each 1.5 ml dose contains $\geq 10^{6.0}$ $CCID_{50}$ human rotavirus RIX4414 strain (live attenuated).

Uses: Active immunisation of infants aged 6 to 24 weeks, against gastro-enteritis due to rotavirus infection.

Dosage and administration: Two oral doses, given at least 4 weeks apart. First dose to be given from 6 weeks of age and second dose, preferably before age 16 weeks. At latest, course must be completed by 24 weeks. For preterm infants and special populations, see SPC. Rotarix must not be injected.

Side effects: See SPC for full details. Common: diarrhoea, irritability. Serious: intussusception, rectal bleeding.

Contraindications: Hypersensitivity to rotavirus vaccines, history of, or predisposition to intussusception, Severe Combined Immunodeficiency (SCID) disorder. Postpone in subjects with acute severe febrile illness, diarrhoea or vomiting. See SPC for full details.

Precautions: Gastrointestinal illnesses or growth retardation, any symptoms indicative of intussusception (severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever). Administer with caution to individuals who are immunodeficient or with immunodeficient close contacts as vaccine virus excreted in stools may be transmitted to seronegative individuals. There is a potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. The vaccine contains sucrose as an excipient. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this vaccine. Rotarix should under no circumstances be injected.

Legal category: POM. MA number: EU/1/05/330/009.

Presentation and basic NHS cost: 1.5 ml of oral suspension in a squeezable tube (polyethylene) fitted with a membrane and a tube cap (polypropylene).NHS Cost: £34.76 MA holder: GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89 B-1330 Rixensart, Belgium.

For the UK, further information is available from Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221 441. For Ireland, please contact 1800 244 255.

UK/ROT/0001/17 Date of preparation: November 2017

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard, or search for MHRA yellow card in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.