Rotarix (live attenuated rotavirus vaccine (oral)) PRESCRIBING INFORMATION

Please find below:

1. **PRESCRIBING INFORMATION for Great Britain (GB)**
2. **PRESCRIBING INFORMATION for Northern Ireland** (***which is located below the GB Prescribing Information***)

PRESCRIBING INFORMATION - Great Britain

Please consult the Summary of Product Characteristics (SPC) before prescribing.

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)**.** Contains 1073 mg sucrose, 32 mg sodium, 10 µg glucose and 0.15 µg of phenylalanine per dose.
Indication: Active immunisation of infants aged 6 to 24 weeks for prevention of gastroenteritis due to rotavirus infection.
Dosage and administration: The vaccination course consists of two doses. Rotarix is for oral use only. The first dose may be administered from the age of 6 weeks. There should be an interval of at least 4 weeks between doses. The vaccination course should preferably be given before 16 weeks of age but must be completed by the age of 24 weeks. Rotarix should not be used in children over 24 weeks of age. For preterm infants and special populations, see SPC.
Contraindications: Hypersensitivity to the active substance, any of the excipients listed in the SmPC; hypersensitivity after previous administration of rotavirus vaccines; history of intussusception or uncorrected congenital malformation of the gastrointestinal tract that would predispose for intussusception; severe Combined Immunodeficiency (SCID) disorder. Postpone administration in infants suffering from acute severe febrile illness, diarrhoea or vomiting.
Special warnings and precautions: Gastrointestinal illnesses or growth retardation any symptoms indicative of intussusception (severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever). Healthcare professionals should follow up for any symptoms of intussusception particularly in first 7 days after rotavirus vaccination. In individuals who are immunodeficient, including *in utero* exposure to an immunosuppressive treatment, consider risks/benefits of Rotarix vaccination. Caution in infants with immunodeficient close contacts. Potential risk of apnoea with Rotarix administration in very premature infants (≤ 28 weeks of gestation) so consider respiratory monitoring for 48-72h, particularly for those with a previous history of respiratory immaturity. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this vaccine. This vaccine contains phenylalanine which may be harmful for patients with phenylketonuria (PKU). Rotarix should under no circumstances be injected. **Interactions:** For information on the concomitant use of *Rotarix* with other vaccines please refer to the SPC.
Pregnancy and lactation: Not intended for use in adults, no data on the use of Rotarix during pregnancy and lactation.
Adverse reactions: See SPC for full details. Common: diarrhoea, irritability. Serious: intussusception, rectal bleeding, apnoea in very premature infants (≤ 28 weeks of gestation), gastroenteritis with vaccine viral shedding in infants with SCID**.**
Legal category: POM. **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 Number**: PLGB 19494/0256. **MA holder**: GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom. For the UK, further information is available from Customer Contact Centre, GlaxoSmithKline, customercontactuk@gsk.com; Freephone: 0800 221 441. Rotarix is a registered trademark of the GlaxoSmithKline group of companies.
Date of preparation: March 2024.
Ref: PI-0514 (V10.0).

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

PRESCRIBING INFORMATION – Northern Ireland

Please consult the Summary of Product Characteristics (SPC) before prescribing.

Rotarix Live attenuated rotavirus vaccine (oral). **Composition**: Each 1.5 ml dose contains ≥$10^{6.0}$ $CCID_{50}$ human rotavirus RIX4414 strain (live, attenuated). Contains 1073 mg sucrose, 32 mg sodium, 10 µg glucose and 0.15 µg of phenylalanine per dose**.**

Indication: Active immunisation of infants aged 6 to 24 weeks for prevention of gastroenteritis due to rotavirus infection.

Dosage and administration: The vaccination course consists of two doses. Rotarix is for oral use only. The first dose may be administered from the age of 6 weeks. There should be an interval of at least 4 weeks between doses. The vaccination course should preferably be given before 16 weeks of age but must be completed by the age of 24 weeks. Rotarix should not be used in children over 24 weeks of age. For preterm infants and special populations, see SPC.

Contraindications: Hypersensitivity to the active substance, any of the excipients listed in the SmPC; hypersensitivity after previous administration of rotavirus vaccines; history of intussusception or uncorrected congenital malformation of the gastrointestinal tract that would predispose for intussusception; severe Combined Immunodeficiency (SCID) disorder. Postpone administration of Rotarix in infants suffering from acute severe febrile illness, diarrhoea or vomiting.

Special warnings and precautions: Gastrointestinal illnesses or growth retardation, any symptoms indicative of intussusception (severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever). Healthcare professionals should follow up for any symptoms of intussusception particularly in first 7 days after rotavirus vaccination. In individuals who are immunodeficient, including *in utero* exposure to an immunosuppressive treatment, consider risks/benefits of Rotarix vaccination. Caution in infants with immunodeficient close contacts. Potential risk of apnoea with Rotarix administration in very premature infants (≤ 28 weeks of gestation) so consider respiratory monitoring for 48-72h, particularly for those with a previous history of respiratory immaturity. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this vaccine. This vaccine contains phenylalanine which may be harmful for patients with phenylketonuria (PKU). Rotarix should under no circumstances be injected. **Interactions:** For information on the concomitant use of *Rotarix* with other vaccines please refer to the SPC.

Pregnancy and lactation: Not intended for use in adults, no data on the use of Rotarix during pregnancy and lactation.

Adverse reactions: See SPC for full details. Common: diarrhoea, irritability. Serious: intussusception, rectal bleeding**,** apnoea in very premature infants (≤ 28 weeks of gestation); gastroenteritis with vaccine viral shedding in infants with SCID**.**

Legal category: POM. **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 Numbers**: EU/1/05/330/005-012. **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, customercontactuk@gsk.com; Freephone: 0800 221 441. Rotarix is a registered trademark of the GlaxoSmithKline group of companies.

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