PRESCRIBING INFORMATION

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

Priorix Measles, mumps and rubella vaccine (live). **Composition**: Live attenuated measles virus (Schwarz strain; $\geq 10^{3.0}$ $CCID_{50}$[3]); live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain; $\geq 10^{3.7}$ $CCID_{50}$[3]); live attenuated rubella virus (Wistar RA 27/3 strain; $\geq 10^{3.0}$ $CCID_{50}$[3]). Trace amount of neomycin; excipients with known effect (9mg sorbitol, 6.5ng para-aminobenzoic acid, 334µg phenylalanine).

Uses: Active immunisation of children from the age of 9 months or older, adolescents and adults against measles, mumps and rubella.

Dosage and administration: Reconstitution required. 0.5ml should be injected subcutaneously. May be given intramuscularly (deltoid or anterolateral area of thigh); SC if thrombocytopaenia or coagulation disorder. Second dose to be given according to official recommendations - for ages 9-12 months, 2nd dose recommended in 2nd year of life, 4-12 weeks after initial dose.

Contraindications: Hypersensitivity to any component of the vaccine or neomycin, severe immunodeficiency, pregnancy, acute severe febrile illness.

Special warnings and precautions: Record name and batch. Medical treatment to be available in case of anaphylaxis. Allow alcohol and disinfecting agents to evaporate before injection. Infants <1yr may not respond sufficiently to vaccine components. Use with caution in those with CNS disorder, family history or susceptibility to febrile convulsions and those who have allergy to egg products. Limited protection possible if used within 72 hours of exposure to measles. Syncope can occur before or after vaccination, especially in adolescents. Protective immune response may not be elicited in all vaccinees. DO NOT administer intravascularly. Consider risk:benefit for those with thrombocytopenia as condition may worsen, and for those with selected immune deficiencies. Pharyngeal excretion of rubella and measles vaccine virus can occur, with no evidence of transmission, and of rubella vaccine virus via breastmilk / transplacentally, with no evidence of disease. Para-aminobenzoic acid may cause allergic reactions. Phenylalanine may be harmful in phenylketonuria. Contains <1mmol sodium and <1mmol potassium.

Interactions: can be given concomitantly with DTPa-HBV-IPV/Hib, DTPa, dTPa, Hib, IPV, HBV, HAV MenB, Menc, MenACWY,VZV, OPV and pneumococcal conjugate vaccines (see SPC for full names). Increased risk of adverse reactions with MenB – consider separate administration. Use separate injection site if simultaneously using other vaccines or leave interval of >1 month for live vaccines if not co-administering. Tuberculin test at same time or delay 6 weeks after vaccination. Delay use in subjects receiving human gamma globulins or blood transfusions.

Pregnancy and lactation: Not evaluated in fertility studies. Pregnant women should not be vaccinated. Avoid pregnancy for one month following vaccination. Virus may be secreted through breastmilk with no evidence of disease. Evaluate risk:benefit if vaccinating mother of breast-feeding immunodeficient infant.

Adverse Reactions: See SPC for full details. *Very common*: Injection site redness; fever ≥38°C (rectal) or ≥37.5°C (axillary/oral). *Common*: Upper respiratory tract infection; rash; injection site pain and swelling; fever ≥39.5°C (rectal) or ≥39°C (axillary/oral). *Serious*: Febrile convulsions (rare), meningitis, orchitis, epididymitis, thrombocytopenia, anaphylaxis, neurological disorders including Guillain Barré syndrome, vasculitis.

Legal Category: POM. **MA number:** PL 10592/0110. **NHS Cost:** £7.64. **MA Holder:** SmithKline Beecham Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS. Trading as GlaxoSmithKline UK. **Further information is available from:** The GSK Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. Priorix is a registered trademark of the GlaxoSmithKline group of companies.

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/, 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.