Prescribing Information: See Summary of Product Characteristics before prescribing

Varilrix varicella vaccine (live). Varilrix powder and solvent for solution for injection in pre-filled syringe. **Composition**: After reconstitution, one dose (0.5 mL) contains: varicella-zoster virus Oka strain (live, attenuated) not less than $10^{3.3}$ PFUs, 6mg of sorbitol, 331 µg of phenylalanine per dose. This vaccine contains a trace amount of neomycin. **Uses**: Active immunisation against varicella of healthy subjects from 12 months of age (9 months in special circumstances), for post-exposure prophylaxis within 72 hours or high-risk individuals. **Dosage and Administration**: Use according to official recommendations. Two-dose schedule with interval of ≥6 weeks but never < 4weeks (≥3 month interval in children aged 9-11 months). High risk individuals may benefit from re-immunisation. Requires reconstitution. For subcutaneous (SC) or intramuscular use (SC in those with bleeding disorder), preferably into deltoid region or anterolateral region of thigh. **Contraindications**: Severe immunodeficiency states such as total lymphocyte count <1200/mm^3, subjects with evidence of lack of cellular immune competence, (e.g. clinically manifest HIV, leukaemias, lymphoma, blood dyscrasias), on immunosuppressive therapy, with severe combined immunodeficiency or agammaglobulinemia, AIDS or HIV with low CD4 count. Hypersensitivity to the active substance, any excipients, neomycin, or to previous varicella vaccine; pregnancy (additionally, avoid becoming pregnant for 1 month after vaccination). **Precautions**: Record name and batch for traceability. Varilrix must not be administered intravascularly or intradermally. Postpone if acute, severe febrile illness. Syncope may occur before/after administration. Medical treatment/supervision to be available in case of anaphylaxis. Allow disinfecting agents to evaporate before administration. Limited protection up to 72 hours after exposure to infection. Breakthrough disease may occur. Vaccinees (especially if rash develops) may transmit vaccine viral strain to contacts – avoid high-risk individuals for up to 6 weeks. Consider risk-benefit profile for some immunocompromised patients. Phenylalanine may be harmful for individuals with phenylketonuria. **Interactions:** Delay if receiving immunoglobulins or blood transfusion for >3 months. Salicylates should be avoided for 6 weeks after vaccination due to risk of Reye's Syndrome. Different injectable vaccines should always be administered at different injection sites. If not administered concomitantly, leave interval of >1 month between Varilrix and measles containing vaccine. Do not administer with other live vaccines in subjects at high risk of severe varicella. Tuberculin test to be carried out prior/simultaneous to vaccination to avoid risk of false negative. **Side Effects**: See SPC for full details. Very common: pain, erythema. Common: Rash, pyrexia (oral/axillary ≥37.5◦C; rectal ≥38.0◦C), injection site swelling. Serious: thrombocytopenia, anaphylaxis/hypersensitivity, encephalitis, stroke seizure, cerebellitis, cerebellitis-like symptoms, Henoch Schonlein Purpura, Kawasaki syndrome, erythema multiforme. **Legal Category:** POM. **MA number:** Vaccine: PL 10592/0121 Diluent: PL 10592/0021. **Presentation and basic NHS Cost:** Powder in a single-dose glass vial + 0.5 ml of solvent in a pre-filled syringe. 1 x pack: £27.31. **MA Holder:** SmithKline Beecham Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. Trading as: GlaxoSmithKline UK. **Further information is available from:** Customer Contact Centre, customercontactuk@gsk.com, Freephone 0800 221 441.

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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.