VARIVAX® [Varicella Vaccine (live)]

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing

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 MSD UK (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Vial containing lyophilised preparation of live attenuated varicella virus and prefilled syringe containing Water for Injections. After reconstitution, one dose (0.5 mL) contains no less than 1350 PFU varicella virus.

USES
Vaccination against varicella from 12 months of age. Can be administered from 9 months of age under special circumstances e.g. to conform with national vaccination schedules or in outbreak situations. May also be given to susceptible individuals who have been exposed to varicella. Vaccination within 3 days of exposure may prevent a clinically apparent infection or modify the course of the infection. Limited data indicate that vaccination up to 5 days after exposure may modify the course of the infection. Use in accordance with official recommendations.

DOSAGE AND ADMINISTRATION
Inject intramuscularly or subcutaneously. Administer subcutaneously in patients with thrombocytopenia or any coagulation disorder. Do not inject intravascularly.
9 to 12 months of age: 2 doses, minimum of 3 months apart.
12 months to 12 years of age: 2 doses, minimum of 1 month apart.
12 months to 12 years of age with asymptomatic HIV infection [CDC Class 1] with an age-specific CD4+ T-lymphocyte percentage ≥25%: 2 doses given 12 weeks apart.
13 years of age and older: 2 doses, given 4-8 weeks apart. If the interval between doses exceeds 8 weeks, give the second dose as soon as possible.

CONTRA-INDICATIONS
Hypersensitivity to any varicella vaccine, to any of the excipients or to neomycin. Blood dyscrasias, leukaemia, lymphomas, or other malignant neoplasms affecting the hemic or lymphatic systems. Immunosuppressive therapy. Severe humoral or cellular immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia and AIDS or symptomatic HIV infection or an age-specific CD4+ T-lymphocyte percentage in children below 12 months: CD4+ <25%; 12-35 months: CD4+ < 20%; 36-59 months: CD4+ < 15%. Family history of congenital or hereditary immunodeficiency unless immune competence demonstrated. Active untreated tuberculosis. Fever >38.5ºC. Pregnancy. Avoid pregnancy for 1 month post vaccination.

PRECAUTIONS
Ensure appropriate medical treatment and supervision are available in the rare event of anaphylaxis. Patients should avoid salicylates for 6 weeks post vaccination. Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks of acquiring and transmitting the wild-type varicella virus. Immunocompromised patients who have no contraindication for this vaccination may not respond as well as immunocompetent subjects and should be monitored carefully for signs of varicella. Transmission of the vaccine virus may rarely occur with/without development of varicella-like rash and result in infection including disseminated disease in susceptible contacts including healthy as well as high-risk individuals. Vaccine recipients should avoid close association with susceptible high-risk individuals for up to 6 weeks after vaccination. If varicella vaccine (live) is not given concomitantly with measles, mumps, and rubella virus vaccine live, leave a 1-month interval between the 2 live virus vaccines. Defer vaccination for 5 months post blood/ plasma transfusions, or administration of normal human immune globulin or varicella zoster immune globulin (VZIG). Administration of VZIG or other IG preparations should be avoided within 1 month of a dose of Varivax unless essential.
Pregnancy and lactation: do not use during pregnancy and avoid pregnancy for 1 month post vaccination. Not recommended for breastfeeding mothers.

SIDE EFFECTS

Refer to SmPC for complete information on side-effects.

Healthy individuals 12 months to 12 years of age (1 dose): *Very common*: Fever. *Common:* Upper respiratory infection; rash, measles /rubella-like rash; varicella-like rash (generalised median 5 lesions); injection site erythema, rash, pain/tenderness/soreness, swelling and varicella-like rash (injection site median 2 lesions); irritability.

Healthy individuals 12 months to 12 years of age (2 doses received ≥ 3 months apart): Serious side effects temporally associated with the vaccination: Diarrhoea; febrile seizure; fever; post-infectious arthritis; vomiting.

Healthy individuals 13 years of age and older (majority received 2 doses 4 to 8 weeks apart): *Very common*: Fever ≥ 37.7°C oral; injection-site erythema, soreness and swelling. Common side effects: varicella-like rash (generalised median 5 lesions); injection-site rash, pruritus and varicella-like rash (injection site median 2 lesions). Side effects reported during post-marketing surveillance that may potentially be serious include: thrombocytopenia, pneumonia, anaphylaxis, cerebrovascular accident, febrile and non-febrile convulsions, Guillain-Barré syndrome, transverse myelitis, Bell's palsy, ataxia, Stevens-Johnson syndrome, erythema multiforme, Henoch-Schönlein purpura; herpes zoster and disseminated disease e.g. aseptic meningitis and encephalitis in immunocompromised or immunocompetent individuals; necrotizing retinitis in immunocompromised individuals; secondary transmission.

PACKAGE QUANTITIES AND BASIC NHS COST

Single vial of vaccine and prefilled syringe of diluent in a pack of one: £30.28.

Marketing Authorisation number:

PL 53095/0009

Marketing Authorisation Holder:

Merck Sharp & Dohme (UK) Limited,
120 Moorgate, London EC2M 6UR,
United Kingdom

Legal category: POM

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