VARIVAX® [Varicella Vaccine (live)]

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics 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: 01992 467272).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Vial containing a lyophilised preparation of live attenuated varicella virus (Oka/Merck strain) and a prefilled syringe containing Water for Injections. After reconstitution, one dose (0.5 mL) contains no less than 1350 PFU (Plaque-forming units) varicella virus.

USES
Vaccination against varicella in individuals from 12 months of age. Can be administered to infants from 9 months of age under special circumstances, such as to conform with national vaccination schedules or in outbreak situations. May also be administered 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.
Individuals from 9 to 12 months of age: should receive 2 doses, a minimum of 3 months apart.
Individuals from 12 months to 12 years of age: should receive 2 doses, a minimum of 1 month apart.
Individuals 12 months to 12 years of age with asymptomatic HIV infection [CDC Class 1] with an age-specific CD4+ T-lymphocyte percentage ≥25%: should receive 2 doses given 12 weeks apart.
Individuals from 13 years of age and older: should receive 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
History of hypersensitivity to any varicella vaccine, to any of the excipients or to gelatine or neomycin. Blood dyscrasias, leukaemia, lymphomas of any type, or other malignant neoplasms affecting the hemic or lymphatic systems. Individuals receiving 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%; children between 12-35 months: CD4+ < 20%; children between 36-59 months: CD4+ < 15%. Individuals with a family history of congenital or hereditary immunodeficiency unless immune competence has been demonstrated. Active untreated tuberculosis. Any illness with 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. Vaccine recipients should avoid salicylates for 6 weeks after 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; therefore, some of these patients may acquire varicella in case of contact, despite appropriate vaccine administration. Monitor carefully for signs of varicella. Transmission of the vaccine virus may rarely occur between healthy vaccinees who develop or do not develop a varicella-like rash and healthy susceptible contacts, pregnant contacts and immunosuppressed contacts. Vaccine recipients should therefore avoid close association with susceptible high-risk individuals for up to 6 weeks after vaccination. If varicella vaccine (live) (Oka/Merck strain) is not given concomitantly with measles, mumps, and rubella virus vaccine live, a 1-month interval between the 2 live virus vaccines should be observed.

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 Summary of Product Characteristics 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): The following serious side effects temporally associated with the vaccination were reported in individuals 12 months to 12 years of age given varicella vaccine (live) (Oka/Merck strain): 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). Other reported side effects (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 and herpes zoster. During marketed use of the vaccine varicella (vaccine strain) has been reported and in immunocompromised individuals complications have occurred including herpes zoster and disseminated disease e.g. aseptic meningitis and encephalitis. The vaccine virus may rarely be transmitted to contacts of vaccinees who may develop a varicella-like rash. Necrotizing retinitis has been reported post-marketing in immunocompromised individuals.

PACKAGE QUANTITIES AND BASIC NHS COST

Single vial of vaccine and prefilled syringe of diluent in a pack of one, basic NHS cost £30.28.

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PL 00025/0637

Marketing Authorisation Holder:
Merck Sharp & Dohme Limited,
Hertford Road, Hoddesdon,
Hertfordshire EN11 9BU, United Kingdom

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