ZOSTAVAX®
Shingles (herpes zoster) 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: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Vial containing lyophilised live attenuated varicella-zoster virus and pre-filled syringe containing water for injections. After reconstitution, one dose (0.65 ml) contains no less than 19400 PFU (plaque-forming units) varicella-zoster virus.

USES
Active immunisation for the prevention of herpes zoster ("zoster" or shingles) and herpes zoster-related post-herpetic neuralgia (PHN) in individuals 50 years of age or older.

DOSAGE AND ADMINISTRATION
Give a single dose subcutaneously (SC) or intramuscularly (IM), preferably in the deltoid region. Administer subcutaneously in patients with severe thrombocytopenia or any coagulation disorder. Do not inject intravascularly. Administer immediately after reconstitution, to minimise loss of potency. In use stability has been demonstrated for 30 minutes when stored at 20–25ºC. Discard reconstituted vaccine if it is not used within 30 minutes.

CONTRA-INDICATIONS
History of hypersensitivity to the active substance, to any of the excipients or trace residuals (e.g. neomycin). Primary and/or acquired immunodeficiency states e.g. lymphoma, HIV/AIDS. Immunosuppressive therapy (including high-dose corticosteroids). Active untreated tuberculosis. Pregnancy.

PRECAUTIONS
Ensure appropriate facilities and medication are available in case of anaphylaxis. Zostavax is not indicated for the treatment of zoster or PHN. Delay immunisation in presence of moderate to severe acute febrile illness or infection. Give subcutaneously to individuals with severe thrombocytopenia or any coagulation disorder. In clinical trials with Zostavax, transmission of the vaccine virus has not been reported. Post-marketing experience with varicella vaccines suggest that transmission of vaccine virus may occur rarely between vaccinees who develop a varicella-like rash and susceptible contacts (for example, VZV-susceptible infant grandchildren). Transmission of vaccine virus from varicella vaccine recipients who do not develop a varicella-like rash has also been reported. This is a theoretical risk for vaccination with Zostavax. Weigh risk of transmitting the attenuated vaccine virus from vaccinated individual to a susceptible contact against the risk of developing natural zoster and potentially transmitting wild-type VZV to a susceptible contact. Vaccination may not result in protection in all recipients. Reduced immunogenicity of Zostavax has been reported after concurrent administration with 23-valent pneumococcal polysaccharide vaccine in a small clinical trial. Data collected in a large observational study did not indicate an increased risk of developing herpes zoster after concomitant administration of the two vaccines. Zostavax is a live vaccine and administration to individuals who are immunosuppressed or immunodeficient may result in disseminated varicella-zoster virus disease, including fatal outcomes. Carefully evaluate patients who have previously received immune suppressive therapy for the reconstitution of the immune system prior to immunisation. Safety and efficacy not established in adults infected with HIV with or without immunosuppression. *Pregnancy:* not recommended during pregnancy. Pregnancy should be avoided for one month post-vaccination. *Lactation:* risk to newborns/infants cannot be excluded. Weigh benefit of breast feeding for the child against benefit of vaccination for the woman.

SIDE EFFECTS
Refer to Summary of Product Characteristics for complete information on side-effects.
Very common: pain/tenderness, erythema, swelling and pruritus at the injection site. *Common:* warmth, haematoma, induration, pyrexia at the injection site, pain in extremity, arthralgia, myalgia, rash and headache. *Uncommon:* lymphadenopathy (cervical, axillary), nausea. *Rare:* hypersensitivity reactions including anaphylactic reactions,

injection site urticaria. *Very rare:* varicella, herpes zoster (vaccine strain) and necrotizing retinitis (patients on immunosuppressive therapy).

PACKAGE QUANTITIES AND BASIC NHS COST
Pack containing one vial and one pre-filled syringe with two separate needles: £99.96.

Marketing Authorisation number:
Great Britain: PLGB 53095/0085

UK (Northern Ireland): EU/1/06/341/011

Marketing Authorisation Holder:
GB: Merck Sharp & Dohme (UK) Ltd, 120 Moorgate, London EC2M 6UR, United Kingdom
UK(NI): Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

Legal Category: POM

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