Please refer to the next page for Shingrix prescribing information for Northern Ireland

Prescribing information – GB

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

Shingrix Herpes zoster vaccine (recombinant, adjuvanted). Shingrix powder and suspension for suspension for injection. **Composition:** Following reconstitution, one 0.5ml dose contains 50µg Varicella Zoster Virus glycoprotein E antigen adjuvanted with $AS01_B$ (containing 50µg of *Quillaja saponaria* Molina, fraction 21 (QS-21) and 50µg of 3-O-desacyl-4'-monophosphoryl lipid A (MPL).

Uses: Prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older and adults 18 years of age or older at increased risk of HZ. Use of Shingrix should be in accordance with official recommendations.

Dosage and administration: Primary vaccination schedule consists of two doses of 0.5 ml each: an initial dose followed by a 2nd dose 2 months later. If flexibility is needed, second dose can be given between 2-6 months after the first. For those who are or might become immunodeficient/immunocompromised and who would benefit from a shorter schedule, the 2nd dose can be given 1-2 months after the initial dose. Shingrix is for IM administration only. Shingrix must be reconstituted prior to administration. The need for booster doses following the primary vaccination schedule has not been established.

Contra-indications: Hypersensitivity to the active substances or to any of the excipients.

Special warnings and precautions: Shingrix is not indicated for prevention of primary varicella infection. Prior to immunisation, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following administration. Administration of the vaccine should be postponed in subjects suffering from an acute severe febrile illness. A protective response may not be elicited in all vaccinees. The vaccine is for prophylactic use only and is not intended for treatment of established clinical disease. Shingrix should not be administered intradermally or intravascularly. Subcutaneous administration is not recommended; and maladministration via this route may lead to an increase in transient local reactions. Shingrix should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following IM administration. Syncope (fainting) can occur following, or even before, any vaccination. This can be accompanied by neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. In a post-marketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination; available information is insufficient to determine a causal relationship. There are no safety, immunogenicity or efficacy data to support replacing a dose of Shingrix with a dose of another HZ vaccine. There are limited data to support the use of Shingrix in individuals with a history of HZ. Therefore, the benefits and risks of HZ vaccination should be weighed on an individual basis.

Interactions: Can be given concomitantly with unadjuvanted inactivated seasonal influenza vaccine, 23-valent pneumococcal polysaccharide vaccine (PPV23), 13-valent pneumococcal conjugate vaccine (PCV-13) reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa) or COVID-19 messenger ribonucleic acid (mRNA) vaccine. Vaccines should be administered at different injection sites. Fever and shivering were more frequent when PPV23 vaccine is co-administered with Shingrix compared to Shingrix alone. In adults 50 years and above, systemic adverse reactions that are very commonly reported (such as myalgia, fatigue, and headache) and arthralgia (which is uncommonly reported) following administration with Shingrix alone were reported with increased frequency when Shingrix was co-administered with a COVID-19 mRNA vaccine. Concomitant use with other vaccines than those listed above is not recommended due to lack of data.

Ability to drive and use machinery: May have a minor influence on the ability to drive and use machines in the 2-3 days following vaccination.

Pregnancy and lactation: No data in pregnancy, as a precautionary measure, it is preferable to avoid the use of Shingrix during pregnancy. The effect on breast-fed infants of administration of Shingrix to their mothers has not been studied.

Adverse reactions: See SPC for details of other adverse reactions. *Very Common*: Headache, GI symptoms (including nausea, vomiting, diarrhoea and/or abdominal pain), myalgia, injection site reactions (such as pain, redness, swelling), fatigue, chills, fever. *Common:* injection site pruritus, malaise. *Serious:* hypersensitivity reactions including rash, urticaria, angioedema.

Legal category: POM. **Presentation and basic NHS cost:** Available in a pack size of 1 vial of powder plus 1 vial of suspension, 1 = £160. **Marketing Authorisation Numbers:** PLGB 19494/0263. **Marketing Authorisation Holder:** GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK. **Further information is available from:** GlaxoSmithKline Customer Contact Centre, customercontactuk@gsk.com; Freephone 0800 221 441. Shingrix is a trademark of the GlaxoSmithKline group of companies.

PI-11945: January 2024 (V2.0)

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.

Prescribing information – NI

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

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Contra-indications: Hypersensitivity to the active substances or to any of the excipients.

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Legal category: POM. **Presentation and basic NHS cost:** Available in a pack size of 1 vial of powder plus 1 vial of suspension, 1 = £160. **Marketing Authorisation Numbers:** EU/1/18/1272/001, EU/1/18/1272/002. **Marketing Authorisation Holder:** GlaxoSmithKline Biologicals S.A. Rue de L'Institut 89, b-1330 Rixensart, Belgium. **Further information is available from:** GlaxoSmithKline Customer Contact Centre, customercontactuk@gsk.com; Freephone 0800 221 441. Shingrix is a trademark of the GlaxoSmithKline group of companies.

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