Prescribing information- Great Britain

▼ Arexvy Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)

Please refer to the appropriate Summary of Product Characteristics (SmPC) before prescribing Arexvy.

Presentation: Arexvy Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted). Powder and suspension for suspension for injection. Arexvy powder is white, and the suspension is an opalescent, colourless to pale brownish liquid. **After reconstitution**, one dose, 0.5 mL contains: 120 micrograms of RSVPreF3 antigen with recombinant DNA technology adjuvanted with $AS01_E$ containing 25 micrograms plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) and 25 micrograms 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella Minnesota*.

Indication: Active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older. The use of this vaccine should be in accordance with official recommendations.

Dosage and administration: A single dose of 0.5 mL is administered as an intramuscular injection only, preferably in the deltoid muscle. Arexvy must be reconstituted prior to administration (refer to Section. 6.6 on Arexvy SmPC for further information) The need for revaccination with a subsequent dose has not been established.

Contraindications: Hypersensitivity to the active substances or to any of the excipients (refer to Section 6.1 on Arexvy SmPC for further information).

Special warnings: Prior to immunisation, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Close observation for at least 15 minutes is recommended following vaccination. Administration of vaccine should be postponed in individuals suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination. As with any vaccine, a protective immune response may not be elicited in all vaccinees. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with the vaccination process itself. It is important that precautions are in place to avoid injury from fainting. The vaccine is for prophylactic use only and is not intended for treatment of established clinical disease. **Precautions for use:** Do not administer the vaccine intravascularly or intradermally. No data are available on subcutaneous administration of Arexvy. As with other intramuscular injections, Arexvy should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these individuals. Safety and immunogenicity data on Arexvy are not available for immunocompromised individuals. Patients receiving immunosuppressive treatment or patients with immunodeficiency may have a reduced immune response to Arexvy.

Interactions: Arexvy may be administered concomitantly with seasonal influenza vaccine (quadrivalent, standard dose, unadjuvanted, inactivated). In a randomised study in adults 60 years of age and older, the criteria for non-inferiority of the immune responses in the co-administration versus the separate administration group were met. However, numerically lower RSV A and B neutralising titres and numerically lower influenza A and B haemagglutination inhibition titres were observed when Arexvy and inactivated seasonal influenza vaccine were co-administered than when they were administered separately. The clinical relevance of this finding is unknown. There are no data on co-administration with high dose or adjuvanted seasonal influenza vaccines. If Arexvy is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites. Concomitant administration of Arexvy with other vaccines has not been studied.

Effects on ability to drive and use machines: May have minor influence on the ability to drive and use machines. Some of the effects mentioned (Section 4.8 "undesirable effects" of the Arexvy SmPC) *e.g.,* fatigue, may temporarily affect the ability to drive or use machines.

Fertility, Pregnancy, and breast-feeding: *Fertility:* No data on the effects of Arexvy on human fertility. *Pregnancy:* Arexvy is not recommended during pregnancy. *Breast-feeding/ lactating:* Arexvy is not recommended in breast-feeding/ lactating women.

Undesirable effects: The most commonly reported adverse reactions were injection site pain, fatigue, myalgia, headache, and arthralgia. These adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. Adverse reactions are listed below by MedDRA system organ class and frequency. All *very common* (≥1/10) grade adverse reactions: headache, myalgia, arthralgia, injection site pain, fatigue, *Common* adverse reactions (≥1/100 to <1/10): injection site erythema, injection site swelling, fever, chills, *Uncommon* adverse reactions (≥1/1000 to <1/100): lymphadenopathy, hypersensitivity reactions (such as rash), nausea, abdominal pain, vomiting, injection site pruritis, pain, malaise. Refer to the SmPC for a full list of adverse events.

Overdose: Refer to SmPC. **Legal Category:** POM.
Presentation and basic NHS cost: Available in a pack size of 1 vial of powder plus 1 vial of suspension, 1 = £150 and in a pack size of 10 vials of powder plus 10 vials of suspension, 10 = £1500.
Marketing Authorisation Numbers: PLGB 19494/0316.
Marketing Authorisation Holder: GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom. Arexvy is a trademark of the GlaxoSmithKline group of companies. *Full SmPC available from GSK Limited or from www.medicines.org.uk*
Date of preparation: August 2023
PI Job Bag Number: PI-12038

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 GSK Limited on +44 (0) 800 221 441 or UKSafety@gsk.com

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 be immunodeficient/immunocompromised and whom may 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), pneumococcal conjugate vaccine (PCV-13) or reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa). Vaccines should be administered at different injection sites. Fever and shivering were more frequent when PPV23 vaccine is co-administered with Shingrix. Concomitant use with other vaccines 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 full details. *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. **Date of preparation:** June 2023. **Ref:** PI-7340 (V5).

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 – See Summary of Product Characteristics before prescribing**.**

Boostrix Diphtheria, tetanus, and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content). **Composition:** 0.5ml dose contains suspension of diphtheria toxoid ≥2IU, tetanus toxoid ≥20IU, *Bordetella pertussis* antigens (Pertussis toxoid 8µg, Filamentous Haemagglutinin 8µg, Pertactin 2.5µg). **Indications:** Booster vaccination against diphtheria, tetanus, and pertussis in individuals from 4 years of age; protection against pertussis in early infancy following maternal immunisation during pregnancy. **Dosage and administration**: Administration should be based on official recommendations. A single 0.5ml dose by deep intramuscular (IM) injection, preferably in the deltoid region. **Contraindications:** Hypersensitivity to any component of the vaccine or to formaldehyde which is used in the manufacturing process. Hypersensitivity following previous administration of diphtheria, tetanus, or pertussis vaccines; encephalopathy of unknown aetiology ≤7 days after previous pertussis vaccination; transient thrombocytopenia or neurological complications after previous diphtheria and/or tetanus vaccination. Postpone in case of acute severe febrile illness. **Special warnings and precautions:** See SPC for full list. Always review medical history. Careful consideration required with previous temporal association of adverse events after a pertussis-containing vaccine. Risk-benefit of immunising or deferring vaccination should be carefully weighed in case of new onset or progression of neurological disorder. Appropriate medical treatment and supervision should be available in case of anaphylactic shock. May administer subcutaneously with caution, according to official recommendations, in cases of thrombocytopenia or bleeding disorders. Do not administer intravascularly. Expected immune response may not be obtained in immunosuppressed patients. Syncope can occur. Record product name and batch number. **Interactions:** Refer to SPC for more information. **Pregnancy and breastfeeding:** Boostrix can be used during the second or third trimester of pregnancy in accordance with official recommendations. See SPC for data on disease prevention in infants born to women vaccinated during pregnancy. Data from a randomised controlled clinical trial (341 pregnancy outcomes) and from a prospective observational study (793 pregnancy outcomes) where Boostrix was administered in third trimester found no adverse effect on pregnancy or foetus/newborn. No safety data from prospective clinical studies during the first/second trimester available. Passive surveillance of vaccination in third/second trimester found no adverse effect on pregnancy or foetus/newborn. As with other inactivated vaccines, it is not expected that vaccination with Boostrix harms the foetus at any trimester. Animal studies do not indicate direct or indirect harmful effects in pregnancy, embryonal/foetal development, parturition or post-natal development. Effect of administration during lactation has not been assessed. As Boostrix contains toxoids or inactivated antigens, no risk to the breastfed infant should be expected. The benefits versus the risk should be carefully evaluated. **Adverse reactions:** See SPC for full list and details. Age 4-8 years: *Very common*: irritability, somnolence, injection site reactions (redness and/or swelling) and pain, fatigue. *Common*: anorexia; headache; diarrhoea, vomiting, GI disorders, pyrexia, extensive swelling of vaccinated limb. Age 10-76 years: *very common*: headache; injection site reactions (redness and/or swelling) and pain, fatigue, malaise. *Common*: dizziness; nausea, GI disorders, pyrexia, injection site reactions (injection site mass and abscess sterile). *Serious side effects (post-marketing surveillance):* allergic reactions including anaphylactic and anaphylactoid reactions, hypotonic-hyporesponsiveness episodes, convulsions, angioedema, rare adverse reactions on the central or peripheral nervous system after tetanus toxoid-containing vaccines. **Legal category:** POM. **MA number:** PL 10592/0162. **Presentation and basic NHS cost:** 0.5ml suspension in pre-filled syringe (Type I glass) with a stopper (rubber butyl) with or without needles. **NHS List Price:** £16.32. **MA holder:** SmithKline Beecham Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS. **Further information:** available from the GSK Customer Contact Centre, customercontactuk@gsk.com; Freephone: 0800 221 441. **Ref:** PI-11818. **Date of preparation:** May 2023.

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.

Influsplit Tetra 2023/2024:
Active substance: Influenza split vaccine (inactivated). **Composition:** 1 vaccine dose (0.5 ml) contains influenza virus (inactivated, split) of the following strains: A/ Victoria/**4897/2022** (H1N1)pdm09-like strain (A/ Victoria/**4897/2022**, IVR-238), A/ Darwin/9/2021 (H3N2)-like strain (A/ Darwin/6/2021, IVR-227), B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26), B/Phuket/3073/2013-like strain (B/Phuket/3073/2013), B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, BVR-26) strain (B/Phuket/3073/2013, wild type); 15 µg haemagglutinin per strain. Proliferated in embryonated chicken eggs. **Other ingredients:** Sodium chloride, sodium monohydrogen phosphate x 12 H_2O, potassium dihydrogen phosphate, potassium chloride, magnesium chloride x 6 H_2O, RRR- α - Tocopherol hydrogen succinate, polysorbate 80, octoxinol 10 and water for injections. **Indications:** Influsplit Tetra is used for the prevention of true viral flu (influenza) in adults and children aged 6 months and over, caused by viruses of the two influenza A subtypes and of the two influenza B lineages contained in the vaccine. **Contraindications:** Hypersensitivity to the to the active ingredients, to any of the other ingredients or to other trace ingredients of egg (ovalbumin, chicken protein), formaldehyde, gentamicin sulphate and sodium deoxycholate. In febrile illnesses and acute infections, vaccination should be postponed to a later date. **Side effects: Children 6 to < 36 months:** Very common: loss of appetite, irritability/excitement, drowsiness, pain/redness at the injection site. **Frequent:** fever (≥ 38.0 °C), swelling at the injection site. **Children 3 to < 6 years: Very common:** Irritability/excitedness, pain/ redness/ swelling at the injection site. **Frequent:** loss of appetite, drowsiness, fever (≥ 38.0 °C), induration at the injection site. **Children 6 to < 18 years: Very common:** Muscle pain, fatigue, pain/ redness/ swelling at the injection site. **Frequent:** headache, gastrointestinal symptoms, joint pain, fever (≥ 38.0 °C), chills, induration at the injection site. **Adults ≥ 18 Years: Very common:** muscle pain, pain at injection site, fatigue. **Frequent:** Headache, gastrointestinal symptoms, sweating, joint pain, redness/swelling/. hardening at the injection site, chills, fever. **Prescription only**. Date: June 2023.
GlaxoSmithKline GmbH & Co. KG, 80700 Munich, Germany. de.gsk.com
If necessary, please direct reports of side effects to the GSK hotline: 0800-1223355.