Prescribing information- Northern Ireland

▼ 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: EU/1/23/1740/001 EU/1/23/1740/002
Marketing Authorisation Holder: GlaxoSmithKline Biologicals SA, Rue de l'Institut 89, 1330 Rixensart, Belgium. Arexvy is a trademark of the GlaxoSmithKline group of companies. *Full SmPC available from GSK Limited or from* https://www.emcmedicines.com/en-GB/northernireland/
Date of preparation: August 2023
PI Job Bag Number: PI-12119

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