ABBREVIATED PRESCRIBING INFORMATION

Product name: Alutard SQ® Wasp or Alutard SQ® Bee. Abbreviated Prescribing Information. Please refer to the Summary of Product Characteristics before prescribing. **Pharmaceutical form and composition:** Suspension for injection containing venom extracts from wasp *(Vespula spp)* or honey bee *(A. mellifera)* adsorbed to aluminimum hydroxide. **Therapeutic indications:** Immunotherapy treatment of IgE-mediated allergy to wasp or bee venom confirmed by skin prick test and/or inradermal test and/or specific IgE test. **Posology and method of administration:** Treatment with Alutard SQ® must be performed using subcutaneous injections. The dosage of Alutard SQ® must be individually adjusted. The dosage should depend on the patient's general condition, the allergic anamnesis and the patient's sensitivity to the specific allergen used. **Contraindications:** Hypersensitivity to excipients, malignancy or systemic diseases affecting the immune system. Diseases preventing the treatment of possible anaphylactic reactions such as severe cardiovascular disease. Asthma patients at risk of exacerbation and/or with inadequate symptom control. **Special warnings and precautions for use:** Treatment with Alutard SQ® should be administered under supervision of a doctor experienced in specific immunotherapy. Special care should be given to the risk-benefit assessment with regard to treatment of children younger than 5 years. Due to the risk of potentially fatal anaphylactic reactions, treatment with Alutard SQ® must be carried out in clinics or hospitals where facilities for cardiopulmonary resuscitation are immediately available for use by adequately trained personnel. In patients with increased baseline serum tryptase levels and/or mastocytosis, the risk of systemic allergic reactions and the severity of these may be increased. Patients must be observed for at least 30 minutes after each injection. **Interaction with other medicinal products and other forms of interaction:** ACE inhibitors may exacerbate the response to insect venom, resulting in potentially life threatening allergic reactions to insect stings or venom immunotherapy. Antihistamines and bronchodilators may increase tolerance. Concomitant use of venom immunotherapy and tricyclic antidepressants and MAOIs should be used with caution. No data exists on possible risks of simultaneous immunotherapy with other allergens. **Pregnancy and lactation:** The risk to the mother and the foetus of an anaphylactic reaction must be considered. Treatment should not be initiated during pregnancy. No clinical data is available on the use of Alutard SQ® during lactation. **Undesirable effects:** Generally reactions in connection with the treatment with Alutard SQ® are due to an immunological reaction (local and/or systemic). Very commonly reported adverse reactions in patients treated with Alutard SQ® were local reactions at the injection site. The most serious adverse drug reaction occurring in patients treated with Alutard SQ® is anaphylactic shock which is life threatening. Treatment of a severe systemic reaction (anaphylaxis) must be initiated immediately. Prescribers should consult the summary of product characteristics for a list of adverse reactions. **Excipients:** Sodium chloride, sodium hydrogen carbonate, phenol, water for injection, sodium hydroxide, and aluminium hydroxide (hydrated). **Legal Category:** POM. **Marketing authorisation holder:** ALK-Abelló A/S, Bøge Alle 6–8, DK-2970 Hørsholm, Denmark. UK Office: ALK-Abelló Ltd, 1 Manor Park, Manor Farm Road, Reading, Berkshire, RG2 0NA Telephone 01189 037940. **Marketing authorisation number:** PL10085/0054, PL10085/0055, PL10085/0056 and PL10085/0057. **Price:** 4 x 5ml initiation pack £462.61, 5ml maintenance pack £462.61. **Updated:** July 2019. **Item code** 1363V.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to ALK-Abelló Ltd