GARDASIL®
Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)

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 (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Single dose pre-filled syringe containing 0.5 mL of suspension. Each dose of the quadrivalent vaccine contains highly purified virus-like particles (VLPs) of the major capsid L1 protein of Human Papillomavirus (HPV). These are type 6 (20 μg), type 11 (40 μg), type 16 (40 μg) and type 18 (20 μg).

USES:
From the age of 9 years to prevent premalignant genital lesions (cervical, vulvar and vaginal), premalignant anal lesions, cervical cancers and anal cancers causally related to certain oncogenic HPV types and genital warts (condyloma acuminata) causally related to specific HPV types. Use in accordance with official recommendations.

DOSAGE AND ADMINISTRATION
***Individuals 9 to and including 13 years of age*:** 2-dose schedule (0.5 ml at 0, 6 months).
If the second dose is given earlier than 6 months after the first one, administer a third dose. Can be administered according to a 3-dose schedule (0.5 ml at 0, 2, 6 months). Administer the second dose at least 1 month after the first one and the third dose at least 3 months after the second one. Give all 3 doses within a 1-year period.
Individuals 14 years of age and older: 3-dose schedule (0.5 ml at 0, 2, 6 months).
Administer the second dose at least 1 month after the first dose and the third dose at least 3 months after the second one. All 3 doses should be given within a 1-year period.
Safety and efficacy in children below 9 years not established. If first dose given, completion of Gardasil vaccination course recommended. Need for a booster dose not established. Administer by intramuscular injection, preferably in the deltoid area of the upper arm or in the higher anterolateral area of the thigh. Do not inject intravascularly. Neither subcutaneous nor intradermal administration has been studied.

CONTRA-INDICATIONS:
Hypersensitivity to any component of the vaccine. Hypersensitivity after previous administration of Gardasil. Postpone administration during acute severe febrile illness.

PRECAUTIONS
The decision to vaccinate an individual should take into account the risk for previous HPV exposure and potential benefit from vaccination. Ensure appropriate medical treatment is always available in case of anaphylaxis. Give with caution to individuals with thrombocytopaenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. Syncope (fainting), sometimes associated with falling, can occur before or after vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia, and tonic-clonic limb movements during recovery. Observe vaccinees for approximately 15 minutes after vaccination. Procedures should be in place to avoid injury from faints. Only protects against diseases that are caused by HPV types 6, 11, 16 and 18 and to some limited extent against diseases caused by certain related HPV types. Vaccination is not a substitute for routine cervical screening. Individuals with impaired immune responsiveness may not respond to the vaccine. Vaccination may not result in protection in all recipients. Long-term follow-up studies are currently ongoing to determine the duration of protection. There are no safety, immunogenicity or efficacy data to support interchangeability of Gardasil with other HPV vaccines. *Pregnancy and lactation:* Insufficient data to recommend use during pregnancy; postpone vaccination until after completion of pregnancy. Can be given to breastfeeding women.

SIDE EFFECTS

Refer to Summary of Product Characteristics for complete information on side-effects.

Very common: headache and erythema, pain and swelling at the injection site. *Common:* hematoma and pruritus at the injection site, pyrexia, nausea, and pain in the extremities. *Rare:* urticaria. *Very rare:* bronchospasm. *Not known:* Idiopathic thrombocytopenic purpura, acute disseminated encephalomyelitis, Guillain-Barré Syndrome and hypersensitivity reactions, including anaphylactic/anaphylactoid reactions.

PACKAGE QUANTITIES AND BASIC NHS COST

Single dose pre-filled syringe with two separate needles: £86.50 per dose

Marketing Authorisation number:
Great Britain: PLGB 53095/0024
UK (Northern Ireland): EU/1/06/357/007

Marketing Authorisation Holder:
GB: Merck Sharp & Dohme (UK) Ltd, 120 Moorgate, London EC2M 6UR, UK
UK (NI): MSD VACCINS, 162 avenue Jean Jaurès, 69007 Lyon, France

Legal Category: POM

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