MSD

THE FIRST 9-VALENT HUMAN PAPILLOMAVIRUS (HPV) VACCINE

GARDASIL® 9 contains 9 HPV types that account for 89% of HPV-related anogenital cancers and 90% of genital warts in Europe.[1,2*]

* Cervical, vulval, vaginal and anal cancers caused by oncogenic HPV types 16, 18, 31, 33, 45, 52 & 58 genital warts caused by HPV types 6 & 11. Not all cases of anogenital cancer are caused by HPV. The HPV prevalence is: ~100% in cervical cancer; ~88% in anal cancer; ~19% in vulval cancer; ~71% vaginal cancer.[2]

GARDASIL® 9 is indicated for active immunisation of individuals from the age of 9 years against premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types and genital warts caused by specific HPV types. The indication is based on data in males and females aged 9-26 years.

GARDASIL® 9 is not the vaccine offered in the national immunisation programme. The use of HPV vaccines should be in accordance with official recommendations.

For information on efficacy rates and safety considerations, refer to the Summary of Product Characteristics available on the eMC website.

To order please contact AAH on 0844 561 8899.

GARDASIL®9▼
Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)

GARDASIL® 9▼
Human Papillomavirus 9 valent Vaccine (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: 01992 467272).

PRESENTATION Single dose pre-filled syringe containing 0.5 mL of suspension. Each dose contains highly purified virus-like particles (VLPs) of the major capsid L1 protein of Human Papillomavirus (HPV). These are type 6 (30 µg), type 11 (40 µg), type 16 (60 µg), type 18 (40 µg), type 31 (20 µg), type 33 (20 µg), type 45 (20 µg), type 52 (20 µg) and type 58 (20 µg). **USES** From the age of 9 years to prevent premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine-specific HPV-types and genital warts (condyloma acuminata) caused by specific HPV types. Use in accordance with official recommendations. **DOSAGE AND ADMINISTRATION** ***Individuals 9 to and including 14 years of age at time of first injection:*** **2-dose schedule.** Administer the second dose between 5 and 13 months after the first one. If the second dose is administered earlier than 5 months after the first one, administer a third dose. Can be administered according to a 3-dose schedule (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. Give all 3 doses within a 1-year period. ***Individuals 15 years of age and older at time of first injection:*** **3-dose (0, 2, 6 months) schedule.** 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. If first dose given, complete the vaccination course with Gardasil 9. Need for a booster dose not established. Studies using a mixed regimen (interchangeability) of HPV vaccines were not performed for Gardasil 9. Subjects previously vaccinated with a 3 dose regimen of quadrivalent HPV types 6, 11, 16, and 18 vaccine (Gardasil), hereafter referred to as qHPV vaccine, may receive 3 doses of Gardasil 9. *Paediatric population (children <9 years of age):* safety and efficacy not established. *Population ≥ 27 years of age:* safety and efficacy not studied. 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, subcutaneously or intradermally. **CONTRA-INDICATIONS** Hypersensitivity to any component of the vaccine. Hypersensitivity after previous administration of Gardasil 9 or Gardasil. **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 and supervision are always available in case of anaphylaxis. Give with caution to individuals with thrombocytopaenia or any coagulation disorder because bleeding may occur. Syncope (fainting), sometimes associated with falling, can occur following, or even before, any vaccination, especially in adolescents 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. Postpone administration during acute severe febrile illness. Vaccination may not result in protection in all recipients. Only protect against diseases that are caused by HPV types targeted by the vaccine. The vaccine is for prophylactic use only and is not a substitute for routine cervical screening. There are no data on the use of Gardasil 9 in individuals with impaired immune responsiveness; safety and immunogenicity of a qHPV vaccine have been assessed in individuals aged from 7 to 12 years with HIV. Individuals with impaired immune responsiveness may not respond to Gardasil 9. 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 9 with bivalent or qHPV vaccines. *Pregnancy, lactation and fertility:* 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:* erythema, pain and swelling at the injection site and headache. *Common:* pruritus and bruising at the injection site, dizziness, nausea, pyrexia and fatigue. The post-marketing safety experience with qHPV vaccine is relevant to Gardasil 9 since the vaccines contain L1 HPV proteins of 4 of the same HPV types (6, 11, 16, 18). The following adverse experiences have been spontaneously reported during post-approval use of qHPV vaccine and may also be seen in post-marketing experience with Gardasil 9: idiopathic thrombocytopenic purpura, acute disseminated encephalomyelitis, Guillain-Barré Syndrome and hypersensitivity reactions, including anaphylactic/anaphylactoid reactions, urticaria, bronchospasm. **PACKAGE QUANTITIES AND BASIC NHS COST** Single dose pre-filled syringe with two separate needles: £105.00 per dose **Marketing Authorisation number:** EU/1/15/1007/002 **MAH representative:** Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom **Legal category:** POM **Date of review of prescribing information:** September 2017
PI.GRD9.PFS.17.UK.6036

References: 1. GARDASIL® 9 SmPC, 2017. 2. Hartwig S *et al.* Estimation of the epidemiological burden of HPV-related anogenital cancers, precancerous lesions, and genital warts in women and men in Europe: potential additional benefit of a nine-valent second generation HPV vaccine compared to first generation HPV vaccines. *Papillomavirus Res* 2015; 1:90–100.
VACC-1231710-0008 11/17