



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/76588/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Gardasil 9

human papillomavirus 9-valent vaccine (recombinant, adsorbed)

On 26 March 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for Gardasil 9, intended for active immunisation against human papillomavirus (HPV) diseases caused by 9 types of HPV (see full indication below). The applicant for this medicinal product is Sanofi Pasteur MSD SNC.

Gardasil 9 will be available as a suspension for injection. The active substance of Gardasil 9 is made of human papillomavirus type 6, 11, 16, 18, 31, 33, 45, 52, 58 major capsid L1 proteins in the form of virus-like particles (ATC code: J07BM03). The L1 virus-like particles work by triggering a humoral immune response that is effective against the real viruses when the body is exposed to them. The L1 virus-like particles cannot infect cells, reproduce or cause disease.

The benefits with Gardasil 9 are its ability to protect against 9 HPV types that are known to cause approximately: 90% of cervical cancers, more than 95% of adenocarcinoma in situ, 75-85% of high-grade cervical intraepithelial neoplasia, 85-90% of HPV-related vulvar cancers, 90-95% of HPV related high-grade vulvar intraepithelial neoplasia, 80-85% of HPV-related vaginal cancers, 75-85% of HPV-related high-grade vaginal intraepithelial neoplasia, 90-95% of HPV-related anal cancer, 85-90% of HPV-related high-grade anal intraepithelial neoplasia, and 90% of genital warts.

The most common side effects of Gardasil 9 are headache, and pain, swelling and erythema at the injection site.

The full indication is: "Gardasil 9 is indicated for active immunisation of individuals from the age of 9 years against the following HPV diseases: i) premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types; ii) genital warts (*Condyloma acuminata*) caused by specific HPV types. See sections 4.4 and 5.1 for important information on the data that support these indications. The use of Gardasil 9 should be in accordance with official recommendations".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.