

## **GARDASIL™**

### **Fact Sheet**

#### **How GARDASIL™ works**

GARDASIL™ is a prophylactic quadrivalent human papillomavirus (HPV types 6, 11, 16, 18) recombinant vaccine that contains virus-like particles (VLPs) of the four HPV types. VLPs are empty shells consisting of viral protein, but no viral DNA. They closely simulate HPV and are capable of generating an immune response in the body without causing disease. The vaccine also contains an aluminium-based adjuvant to enhance the immune response.

#### **Indications**

GARDASIL™ is a vaccine indicated in girls and women 9 to 26 years of age for the prevention of infection caused by the human papillomavirus (HPV) types 6, 11, 16, and 18 and the following diseases associated with these HPV types:

- Cervical cancer
- Vulvar and vaginal cancer
- Genital warts (condyloma acuminata)
- Cervical adenocarcinoma *in situ* (AIS) – non invasive cancer
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3 – pre-cancers
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3 – pre-cancers
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3 – pre-cancers
- Cervical intraepithelial neoplasia (CIN) grade 1 – low-grade lesions

#### **Proven effectiveness**

Clinical trials were conducted in more than 27,000 females and males from 33 countries around the world. The key efficacy trials followed 20,541 women, including Canadian women, aged 16 to 26 for up to five years after enrolment.

The studies' primary analyses were conducted in women who received all three vaccinations within one year of enrolment, did not have major deviations from the study protocol and were naïve to the relevant HPV type(s) prior to dose one and one month after dose three (Month 7). Efficacy was studied in the individual studies and in combined analyses and measured starting after the Month 7 visit.

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In the combined analyses, GARDASIL™ prevented 100 per cent of HPV 16- and 18-related cervical pre-cancers and non-invasive cervical cancers (CIN 2/3, and AIS, or adenocarcinoma in situ). There were no cases in the 8,487 women who received GARDASIL™ compared to 53 cases in the 8,460 women who received placebo.

GARDASIL™ prevented 95 per cent of low-grade cervical dysplasia (low-grade lesions) and pre-cancers (CIN 2/3 or AIS) caused by HPV 6, 11, 16 or 18. There were four cases in the 7,858 women who received GARDASIL™ compared to 83 cases in the 7,861 women who received placebo.

GARDASIL™ prevented 99 per cent of cases of genital warts caused by HPV 6 or 11. There was one case in the 7,897 women who received GARDASIL™ compared to 91 cases in the 7,899 women who received placebo.

GARDASIL™ also prevented 100 per cent of HPV 16- and 18-related vulvar and vaginal pre-cancers (VIN 2/3 or VaIN 2/3) in women not previously exposed to the relevant HPV types. There were no cases in the 8,641 women who received GARDASIL™ compared to 24 cases in 8,667 women who received placebo. VIN 2/3 and VaIN 2/3 are the immediate precursors to vulvar and vaginal cancers.

These studies also showed that administration of GARDASIL™ – to women who are already infected with one or more vaccine-related HPV types prior to vaccination – protects them from clinical disease caused by the remaining vaccine types but may not alter the course of an infection that is already present.

### **Proven tolerability**

- Administration of GARDASIL™ was generally well tolerated.
- The most common vaccine-related adverse events are injection site pain, swelling and redness, itching and fever.
- Few subjects (0.1 per cent) discontinued vaccination due to an adverse experience.

### **Administration**

- Three intramuscular injections of 0.5 mL of GARDASIL™ administered by a physician or nurse.
- The second injection should be administered two months after the first and the third injection four months later.

### **Availability**

- GARDASIL™ has been available since August 21, 2006 at a list price of \$134.95 per 0.5 mL dose.