



**GARDASIL<sup>®</sup>**  
Human Papillomavirus Vaccine  
Types 6,11,16,18  
Recombinant, adsorbed

HPV PROTECTION FOR PATIENTS AGED 9 AND ABOVE

## Gardasil<sup>®</sup> for Schools

### Information and support for School Nurses

Dear School Nurse,

As you will be aware, the Department of Health will be supplying Gardasil<sup>®</sup> for the national Human Papillomavirus (HPV) vaccination programme from September 2012 for girls in school year 8 (aged 12 to 13 years) and for all girls up to the age of 18 who have not been previously vaccinated against HPV.

Sanofi Pasteur MSD, the manufacturer of Gardasil<sup>®</sup>, is committed to providing information and support to School Nurses to ensure that they are ready to switch to using Gardasil<sup>®</sup> whilst continuing to run effective HPV vaccination clinics within their schools. We are therefore writing to all School Nurses in advance of the new arrangements coming into force to inform you of the resources available to you from Sanofi Pasteur MSD.

### Information and support available

- **The Gardasil<sup>®</sup> for Schools information pack has been designed to complement the information and materials which are available from the Department of Health. The specific Gardasil<sup>®</sup> materials aim to increase knowledge about the product. These items will be available to order from 9th August 2012.**

**How to run an effective HPV vaccination clinic in schools;**

- a guide written and endorsed by the School and Public Health Nurses Association (SAPHNA). This document provides guidance and practical advice for all School Nurses on maximising the effectiveness of their HPV vaccination clinic

**Gardasil<sup>®</sup> clinical information booklet;**

- providing School Nurses with key clinical and safety data on Gardasil<sup>®</sup>

**Gardasil<sup>®</sup> Q&A;**

- a document to answer frequently asked questions about Gardasil<sup>®</sup> and the HPV vaccination programme

**Gardasil<sup>®</sup> fact sheet;**

- a summary document providing key information on Gardasil<sup>®</sup> in an 'aide memoire' format

**Gardasil<sup>®</sup> - dosing schedule;**

- provides information regarding the three-injection dosing schedule

- In advance of the next school year, Sanofi Pasteur MSD will also provide materials for you to distribute to girls and their parents to help support your school HPV vaccination clinics. The following items will be available to order from 23rd August:

#### HPV vaccination – Important Information for year 8 girls leaflet;

- provides information to girls eligible for the national HPV vaccination programme, to help them understand more about HPV vaccination. This leaflet can also be used for girls up to the age of 18 who are entitled to receive Gardasil®

#### In-school poster;

- to publicise the national HPV vaccination programme to year 8 girls and to show key vaccination clinic dates

#### HPV vaccination – Important information for parents leaflet;

- designed to be sent out with the HPV vaccination consent form. This includes important information on the protection provided by Gardasil®, and acts as a reminder to parents of the importance of their daughter completing the full three-dose course. It also includes information for girls up to the age of 18 who are entitled to receive Gardasil®

#### Post vaccination – ‘What to expect now’ leaflet;

- to be given to girls following their first vaccination. This provides important information on the protection provided by Gardasil®, side effects they may experience post-vaccination, and a reminder that they must complete the three-dose course to gain full protection. This leaflet contains an area to write in their follow-up appointments, plus an area for you to write in your contact details should they have any questions.

- **How to order your Gardasil® materials**

You will be able to place an order for the Gardasil® product materials listed on the previous page and the patient materials listed above from 9th August 2012 by visiting [www.spmsd.co.uk](http://www.spmsd.co.uk) and clicking on the healthcare professionals' page. Alternatively, if you have a medical query regarding Gardasil® please call Sanofi Pasteur MSD Medical Information Department on 01628 587693.

Yours sincerely,

Joanna Troman  
Gardasil® Product Manager  
Sanofi Pasteur MSD



#### ABRIDGED PRESCRIBING INFORMATION

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

Refer to Summary of Product Characteristics for full product information.

**Presentation:** Gardasil is supplied as a single dose pre-filled syringe containing 0.5 millilitre 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). **Indications:** Gardasil is a vaccine for use from the age of 9 years for the prevention of premalignant genital lesions (cervical, vulvar and vaginal) and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types and genital warts (condyloma acuminata) causally related to specific HPV types. The indication is based on the demonstration of efficacy of Gardasil in females 16 to 45 years of age and in males 16 to 26 years of age and on the demonstration of immunogenicity of Gardasil in 9- to 15-year old children and adolescents. **Dosage and administration:** The primary vaccination series consists of 3 separate 0.5 millilitre doses administered according to the following schedule: 0, 2, 6 months. If an alternate schedule is necessary the second dose should be administered at least one month after the first and the third dose at least three months after the second. All three doses should be given within a 1 year period. The need for a booster dose has not been established. The vaccine should be administered by intramuscular injection.

**Contraindications:** Hypersensitivity to any component of the vaccine. Hypersensitivity after previous administration of Gardasil. Acute severe febrile illness. **Warnings and precautions:** The decision to vaccinate an individual should take into account the risk for previous HPV exposure and potential benefit from vaccination. As with all vaccines, appropriate medical treatment should always be available in case of rare anaphylactic reactions. The vaccine should be given with caution to individuals with thrombocytopaenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. Syncope, sometimes associated with falling, has occurred after vaccination with Gardasil; vaccinees should be carefully observed for approximately 15 minutes after vaccination. There is insufficient data to recommend use of Gardasil during pregnancy therefore the vaccination should be postponed until after completion of the pregnancy. The vaccine can be given to breastfeeding women. Gardasil will only protect 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, due to either the use of potent immunosuppressive

therapy, a genetic defect, or other causes, may not respond to the vaccine. As with any vaccine, vaccination with Gardasil may not result in protection in all vaccine recipients. There are no safety, immunogenicity or efficacy data to support interchangeability of Gardasil with other HPV vaccines. **Undesirable effects:** Very common side effects include: headache and at the injection site, erythema, pain and swelling. Common side effects include bruising and pruritus at the injection site, pyrexia, nausea, and pain in the extremity. Rarely urticaria and very rarely bronchospasm has been reported. Idiopathic thrombocytopenic purpura, Guillain-Barré Syndrome and hypersensitivity reactions including, anaphylactic/anaphylactoid reactions have also been reported. For a complete list of undesirable effects please refer to the Summary of Product Characteristics. **Package quantities and basic NHS cost:** Single pack containing one 0.5 millilitre dose pre-filled syringe with two separate needles. **NHS cost:** £86.50 per dose. **Marketing authorisation holder:** Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, F-69007, Lyon, France **Marketing authorisation number:** EU/1/06/357/007 (pre-filled syringe with two separate needles) **Legal category:** POM © Registered trademark **Date of last review:** May 2012

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) Adverse events should also be reported to Sanofi Pasteur MSD, telephone number 01628 785291.