

GARDASIL  
Quadrivalent HPV vaccine.

Introduction.

Gardasil is a giant step forward in trying to prevent the onset of a common and devastating set of illnesses in women. It is the first vaccine designed and proven to prevent a major cancer.

It works by stimulating the body to produce immunity against 4 types of the Human Papilloma Virus (HPV).

HPV is a virus of which there are over 100 types, spread by genital or sexual contact. The infection affects the genital areas and can often go unnoticed and sometimes causes no harm. The virus can however, cause changes in cells (dysplasia) and result in:

- Genital Warts
- Cervical Cancer
- High-grade cervical dysplasia
- High-grade vulvar dysplastic lesions

HPV types 6, 11, 16 and 18 are the causes of 70%to 90% of cervical cancers and genital warts.

How it works.

Gardasil contains HPV proteins produced by recombinant DNA technology. It causes the production of antibodies directed at the above 4 types of HPV. It is not infectious: does not cause the actual HPV disease in recipients or their contacts. It has been shown, in a large population based study, to prevent infection from these 4 virus types and thereby protect from the complications of warts and cervical cancer. The evidence has been impressive enough for the vaccine to be fully licensed and approved in the USA and UK.

It does not however, treat already established disease or infection either directly or indirectly.

Who benefits most.

Gardasil is licensed for girls and women from 9 to 26 years of age. Its safety and efficacy in this age group is excellent and we recommend it. The earlier that immunisation is achieved, the better: ideally before becoming sexually active and risking HPV infection. Hence, seriously consider vaccinating your daughter(s).

Women who are already sexually active will also benefit as they may not have caught all 4 types of HPV as yet.

The vaccine is not yet licensed for males.

Risks.

Listed below are reasons to avoid or postpone the vaccination. Please call us if you have any doubts as the list is not exhaustive.

- Allergy or hypersensitivity to any of the active ingredients could cause an allergic reaction.
- The presence of an acute severe feverish illness poses risks of overwhelming the immune system (a mild cold or cough does not matter).
- Avoid if pregnant or likely to be pregnant (Gardasil can be given to breastfeeding women)
- Also avoid or seek advice if taking any regular medications, have HIV or other illnesses that could affect your immune system.
- Seek advice if you have a bleeding disorder.

### Side effects.

About 10% of recipients can get a fever (high temperature) or redness, pain or swelling at the injection site.

1% recipients may get itching or bleeding at the site.

Rarer complications include bronchospasm (like an asthma attack), urticaria and arthritis.

### Vaccination Course.

Gardasil needs to be injected into the muscle 3 times at the following intervals

- The first dose
- Second dose 2 months later
- Third dose 6 months after the first dose

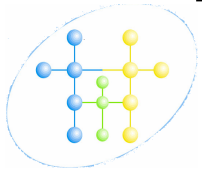
Further booster doses may be required 5 to 10 years later. Research is still on-going in this regard.

Shorter intervals are possible: please ask.

### Important note:

The vaccine does not replace regular cervical screening and practical measures to prevent infection such as condoms etc., when possible.

**November 2006 Dr DD Ratnasinghe**



## Vaccination Registration From: Client Copy

**Please read the enclosed vaccine information and retain for your records. Fill the 3 page Clinic Copy form and send to the address below with the registration fee if applicable.**

Thank you for expressing an interest in the vaccination services offered by Direct Remedies.

The registration process helps to ensure that clients / their children are fully informed of the vaccine and its relevant characteristics such as side effects etc.

It is also extremely useful to have medical and vaccination history for our clinical staff to consider in some detail when planning a vaccination course or deciding on the safety of a particular product for you or your child.

### **Benefits.**

It is an advantage to be able to appreciate the precise degree of protection offered by the vaccines that you are choosing to have. We must emphasise that no vaccine stimulates 100% immunity throughout life. The percentage protection is usually more than 90% for most vaccines but can be as low as 60% in case of the BCG jab.

Some vaccines only cover for certain specific strains of a bacteria or virus. When you read the relevant vaccine information it will be explained in more specific detail.

### **Boosters and Dosing Schedule.**

Most vaccines do not offer lifelong immunity without boosters at appropriate intervals. Please ensure that you are familiar with the schedule for booster for the vaccine(s) that you are interested in.

For some very recent vaccines that have only just been released to healthcare, the need for boosters has not yet been elucidated. In such cases we will keep you updated on our website as manufacturers and research reveals the required schedule.

### **Risks or side-effects.**

Vaccines, like all other medical products, have recognized side effects. While a lot of these are thought to be directly caused by the injected vaccine, other side effects are quite simply loose associations which may have occurred in recipients by chance. They are all important to note in order to make an informed choice. The most common and most severe risks of vaccines in general are:

- Injection site reactions such as swelling, or redness,
- fever (>38°C/100.4°F),
- irritability, drowsiness, restless sleep,
- decreased appetite, vomiting and/or diarrhoea,
- rash or hives,
- Severe, rare allergic reactions,
- Brain inflammation, bone marrow failure (extremely rare)

Please call to clarify any details or discuss with our doctor if required.

Approved and Written: Dr.D.D.Ratnasinghe.

Jan. 2007.

**Vaccination Registration Form: Clinic Copy**

(Please fill this form, sign the authorisation at the end and return to the address below. Leave the last page blank to be filled and signed for consent during each clinic visit)

**Parent/Guardian/Client Details:** Surname: Mr/Mrs/Miss\* \_\_\_\_\_

First Name(s): \_\_\_\_\_ Tel: Landline: \_\_\_\_\_ . Mobile: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_. Postcode: \_\_\_\_\_ . E-mail: \_\_\_\_\_

**Child (If applicable) : Details:** Surname: \_\_\_\_\_

First Name(s): \_\_\_\_\_ . Date of Birth: \_\_\_\_\_ . Male / Female\*

**GP Details:** If you would like us to inform your family doctor of the vaccinations you/your child has received, please supply:

Name of Doctor : \_\_\_\_\_ Tel No.: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_. Post Code: \_\_\_\_\_

**Child/Client's Vaccination History:** What vaccinations have you/your child already had? (Please circle)

Diphtheria (DIP) / Tetanus (TET)/ Whooping Cough (PER) / HIB / BCG / Polio / Men C / Other \_\_\_\_\_

Single Rubella / Single Measles / Single Mumps/ Hep B / Chickenpox / Pnemococcal / Flu / Combined MMR

Any vaccine complications? \_\_\_\_\_

**Family Medical History:** Do any of the following illnesses occur in the family? (Please circle)

**NONE** / Diabetes / Asthma / Crohns / Other bowel disease / Thyroid disease / Cancers / Eczema / Severe allergies

Aspergers / Autism / ADHD / Behavioural disorders / Blood disorders. / Rheumatological disease / Others \_\_\_\_\_

How is your child/yourself related to the relevant person/people above?

\_\_\_\_\_

\_\_\_\_\_

**Vaccination Registration Form: Clinic Copy**

**Your/ your child's Health Record**

Have you/your child been diagnosed with any of the following? (Please circle) **NONE** / **Eczema** / Crohns / Other bowel disease /

Aspergers / Autism / ADHD / Diabetes / Asthma / Thyroid disease / Blood disorder / Malignancy (cancer) / **Other**

Any surgical operations? Yes / No\*. If yes, details: \_\_\_\_\_

What is your/your child's current general health?

Any current medications? Yes / No\*. If yes, details: \_\_\_\_\_

(Certain steroids and cancer treatments are particularly important to note)

Any known allergies? Yes / No\*. If yes, details: \_\_\_\_\_

**Clinic Venue / Location:** Please indicate the name of the clinic venue or location you wish to attend.

Sunbury Clinic (London) \_\_\_ Brighton Clinic \_\_\_ Glasgow Clinic \_\_\_ Newcastle Clinic \_\_\_ York Clinic \_\_\_

Manchester Clinic\_\_\_ Peterborough Clinic\_\_\_ Exeter Clinic\_\_\_ Other Clinic \_\_\_

**Authorisation and Confirmation:** (Signing this section gives us permission to process your application fully)

I authorise Dr.D.D.Ratnasinghe to safeguard and store my / our records in paper and electronic form (Please note that the information will only be used to organise safe and smooth vaccination sessions for you/your child and to conduct internal audits as necessary: all in accordance with the Data Protection Act). Yes / No\*

I confirm that Dr.D.D.Ratnasinghe may import the vaccines on my own/ my child's behalf in accordance with the relevant approved processes. Yes / No\*

Signature of Parent / Guardian / Client: \_\_\_\_\_ Date: \_\_\_\_\_

**Yours Reasons** (Optional): Finally, please share with us your reasons for choosing this vaccine.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Note:** Please send this application form **Direct Remedies Ltd, The Sunbury Clinic, 2 Burgoyne Road, Sunbury-on-Thames, Middlesex, TW16 7PW.**

**Vaccination Registration Form: Clinic Copy**

**CLINIC USE ONLY**

Name of Client/Child: \_\_\_\_\_ Date of Birth \_\_\_\_\_

**1<sup>st</sup> Vaccine:** Vaccination: \_\_\_\_\_ Date: \_\_\_\_\_ Location: \_\_\_\_\_  
Brand Name: \_\_\_\_\_ Lot/Batch no: \_\_\_\_\_ Exp Date: \_\_\_\_\_  
Fit for Vaccination Yes / No\* Site of Injection: \_\_\_\_\_

\* Delete where not applicable

\*I am the parent / legal guardian of the above-named child/ I confirm that all relevant information about the vaccination has been given to me and fully understood by me. I have been given the opportunity to consider the decision and ask any further questions from the doctor or nurse as necessary. **I do consent to my child/me receiving the above vaccine.**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

I Dr/Mr/Ms: \_\_\_\_\_ hereby declare that the above is a true reflection of the informed consent process. All relevant information and outstanding questions have been addressed.

Signature of doctor / nurse: \_\_\_\_\_ Date: \_\_\_\_\_

**2<sup>nd</sup> Vaccine:** Vaccination: \_\_\_\_\_ Date: \_\_\_\_\_ Location: \_\_\_\_\_  
Brand Name: \_\_\_\_\_ Lot/Batch no: \_\_\_\_\_ Exp Date: \_\_\_\_\_  
Fit for Vaccination Yes / No\* Site of Injection: \_\_\_\_\_

\* Delete where not applicable

\*I am the parent / legal guardian of the above-named child/ I confirm that all relevant information about the vaccination has been given to me and fully understood by me. I have been given the opportunity to consider the decision and ask any further questions from the doctor or nurse as necessary. **I do consent to my child/me receiving the above vaccine.**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

I Dr/Mr/Ms: \_\_\_\_\_ hereby declare that the above is a true reflection of the informed consent process. All relevant information and outstanding questions have been addressed.

Signature of doctor / nurse: \_\_\_\_\_ Date: \_\_\_\_\_

**3rd Vaccine:** Vaccination: \_\_\_\_\_ Date: \_\_\_\_\_ Location: \_\_\_\_\_  
Brand Name: \_\_\_\_\_ Lot/Batch no: \_\_\_\_\_ Exp Date: \_\_\_\_\_  
Fit for Vaccination Yes / No\* Site of Injection: \_\_\_\_\_

\* Delete where not applicable

\*I am the parent / legal guardian of the above-named child/ I confirm that all relevant information about the vaccination has been given to me and fully understood by me. I have been given the opportunity to consider the decision and ask any further questions from the doctor or nurse as necessary. **I do consent to my child/me receiving the above vaccine.**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

I Dr/Mr/Ms: \_\_\_\_\_ hereby declare that the above is a true reflection of the informed consent process. All relevant information and outstanding questions have been addressed.

Signature of doctor / nurse: \_\_\_\_\_ Date: \_\_\_\_\_