CANADIAN HEALTH CARE AGENCY LTD

EXPERIENCE THE NORTH

IMPORTANAT INFORMATION ABOUT GARDASIL (www.gardasil.com)

GARDASIL is the only vaccine that may help guard against diseases caused by HPV Types 6, 11, 16 and 18:

- Cervical cancer
- Cervical abnormalities that can sometimes lead to cancer
- Genital warts

HPV Types 16 and 18 causes 70% of cervical cancer cases, and HPV Types 6 and 11 causes 90% of genital warts cases.

Gardasil is for the girls and young women ages 9 to 26

Gardasil may not fully protect everyone and does not prevent all types of cervical cancer, so it is important to continue regular cervical cancer screenings.

Anyone who is allergic to the ingredients of GARDASIL should not receive the vaccine. GARDASIL is not for women who are pregnant.

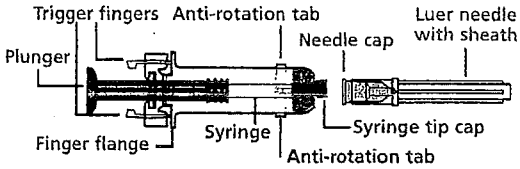
GARDASIL will not treat cervical cancer and genital warts, and will not protect against diseases caused by HPV types.

GARDASIL is given as 3 injections over 6 months and can cause pain, swelling, itching, and redness at the injection site, fever, nausea, and dizziness.

485 Pinebush Rd, Suite 303, Cambridge ON N1T 0A6
PH 519-651-0005; 1-866-502-2422 Fax 1-888-439-2979

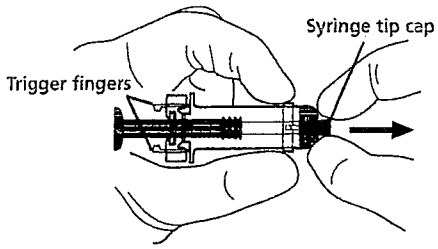
Using the GARDASIL™ Pre-filled Syringe, preassembled with an *UltraSafe Passive*®† delivery system

System Components



NOTE: A 1-inch, 25-gauge needle is supplied with the GARDASIL™ Pre-filled Syringe.

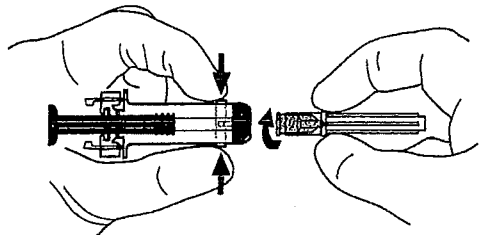
1



- At any of the following steps, avoid contact with the trigger fingers to keep from activating safety device prematurely.
- Remove the syringe tip cap and the cap from the needle (supplied).*
- Visually inspect the syringe, contents and system components (as described above).

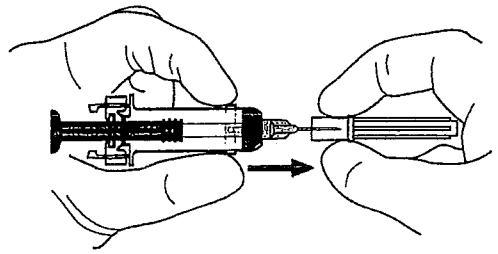
*If a different needle is chosen, it should fit securely on the syringe and be no longer than 1 inch to ensure proper functioning of the safety device.

2



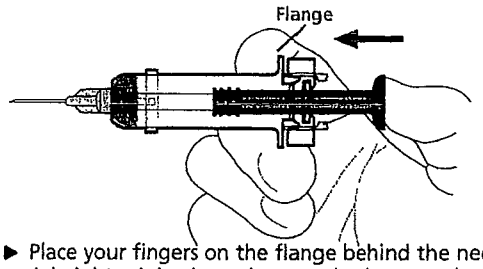
- Insert the needle (supplied).
- Press the 2 anti-rotation tabs near the top of the syringe and twist the needle clockwise to secure it to the syringe.

3



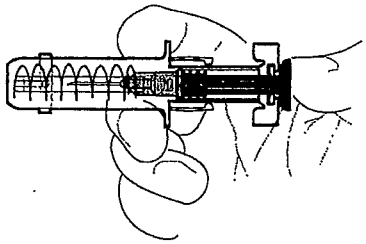
- Remove the sheath of the needle supplied.

4



- Place your fingers on the flange behind the needle. Administer injection using standard protocol.

5



- Depress the plunger until entire dose has been given. The passive guard will not activate unless the entire dose has been given.

6 **After the injection**

- **With the plunger still depressed,** withdraw the needle from the patient.
- After withdrawing the needle from the patient, **slowly** release the plunger.
- The needle guard springs into position to cover the entire needle.
- Peel off the labels and attach them to your patient's chart for documentation of vaccination.
- Dispose of the syringe in the approved sharps container.

NOTE: Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. After thorough agitation, GARDASIL™ is a white, cloudy liquid.

Before administration, please refer to the Product Monograph for complete details.

To order the GARDASIL™ Pre-filled Syringe, preassembled with an *UltraSafe Passive*® delivery system:

- Please contact your **Merck Frosst Vaccine Representative,** or
- The **Merck Frosst Order Desk** at **1-800-463-7251**

If you have any questions about the GARDASIL™ Pre-filled Syringe, preassembled with an *UltraSafe Passive*® delivery system:

- Please contact your **Merck Frosst Vaccine Representative,** or
- The **Merck Frosst Customer Information Centre** at **1-800-567-2594**

GARDASIL™ is a vaccine indicated in girls and women 9-26 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, vulvar, and vaginal cancers, genital warts, cervical adenocarcinoma *in situ* (AIS), cervical intraepithelial neoplasia (CIN) grades 1, 2 and 3, and vulvar and vaginal intraepithelial neoplasia (VIN/VaIN) grades 2 and 3.

The most commonly reported vaccine-related injection-site adverse experiences in clinical trials with GARDASIL™ in females (n=5088), aluminum-containing placebo (n=3470) and saline placebo (n=320), respectively, were pain (83.9%, 75.4%, 48.6%), swelling (25.4%, 15.8%, 7.3%), erythema (24.6%, 18.4%, 12.1%) and pruritus (3.1%, 2.8%, 0.6%). The most commonly reported vaccine-related systemic adverse experience in females was fever: 10.3% for GARDASIL™ (n=5088) vs. 8.6% for aluminum and non-aluminum containing placebo (n=3790).

This vaccine is not intended to be used for treatment of active genital warts; cervical, vulvar, or vaginal cancers; CIN, VIN, or VaIN.

This vaccine will not protect against diseases that are not caused by HPV.

Pregnancy should be avoided during the vaccination regimen for GARDASIL™.

As for any vaccine, vaccination with GARDASIL™ may not result in protection in all vaccine recipients.

†Trademark of Merck & Co., Inc. Used under license.

‡Ultrasafe Passive® is a Registered Trademark of Safety Syringes, Inc.

PLEASE CONSULT THE PRESCRIBING INFORMATION FOR INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND DOSING GUIDELINES.

PRESCRIBING INFORMATION TO BE LEFT WITH THE HEALTH-CARE PROFESSIONAL.

Reference: 1. Safety Syringes, Inc.(TM). UltraSafe Passive‡ Delivery System Directions for Use. Available at: www.safetysyringes.com

Please visit our website at: **www.merckfrosst.com**

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Merck Frosst Canada Ltd., Kirkland, Quebec

PAAB

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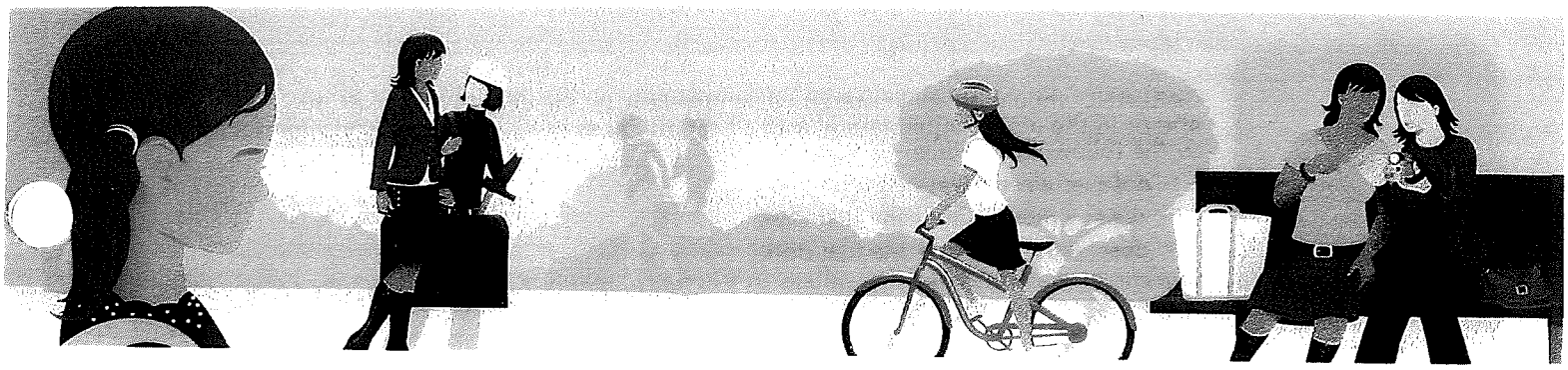
10-07-HPV-06-CDN-84140354-CD

GARDASIL™
[Quadrivalent Human Papillomavirus (Types 6,11,16,18) Recombinant Vaccine]



20,541 young women 16 to 26 years of age participated in 4 Phase II and III worldwide clinical studies. Combined analyses* showed...

GARDASIL® — highly effective in helping protect against HPV types 6, 11, 16, and 18 and the following consequences:

HPV 16- or 18-related

CERVICAL CANCER**,***

100%

EFFECTIVE AGAINST

HPV 16- or 18-related CIN 2/3 or AIS[1,†]

(GARDASIL®: [n=8487] 0 cases, placebo [n=8460] 53 cases; 95% CI: 92.9-100.0)[1,*]

CIN 2/3 and AIS are the immediate and necessary precursors of invasive squamous cell carcinoma and invasive adenocarcinoma of the cervix, respectively.

VULVAR/VAGINAL CANCER***

100%

EFFECTIVE AGAINST

HPV 16- or 18-related VIN 2/3 or VaIN 2/3[2]

(GARDASIL®: [n=7769] 0 cases, placebo [n=7741] 10 cases; 95% CI: 55.5-100.0)[2,*]

VIN 2/3 and VaIN 2/3 are the immediate precursors to HPV-related vulvar and vaginal cancer, respectively.

HPV types 16 and 18 cause approximately:
- 70% of cervical cancer, AIS, CIN 3, VIN 2/3 and VaIN 2/3 cases;[1] and
- 50% of CIN 2 cases.[1]

HPV 6-, 11-, 16-, or 18-related

CERVICAL DYSPLASIA***

95%

EFFECTIVE AGAINST

HPV 6-, 11-, 16-, 18-related CIN (CIN 1, CIN 2/3) or AIS[1,]**

(GARDASIL®: [n=7858] 4 cases, placebo [n=7861] 83 cases; 95% CI: 87.2-98.7)[1,*,**]

HPV types 6, 11, 16, and 18 cause approximately:
- 35 to 50% of all CIN 1, VIN 1 and VaIN 1 cases.[1]

GENITAL WARTS***

99%

EFFECTIVE AGAINST

HPV 6-, 11-, 16-, or 18-related genital warts[3]

(GARDASIL®: [n=7897] 1 case, placebo [n=7899] 91 cases; 95% CI: 93.7-100.0)[3,*]

HPV types 6 and 11 cause approximately:
- 90% of genital warts cases.[1,3]

Dosage and Administration	GARDASIL® should be administered intramuscularly (in the deltoid region of the upper arm or in the higher anterolateral area of the thigh) as three separate 0.5 mL doses according to the following schedule: • 1st dose: at elected date • 2nd dose: 2 months after the first dose • 3rd dose: 6 months after the first dose Individuals are encouraged to adhere to the Day 0, Month 2 and Month 6 vaccination schedule. If a deviation from the recommended schedule occurs, it is recommended that the second dose be administered at least 1 month after the first dose, and the third dose be administered at least 3 months after the second dose. All 3 doses should be given within a 1-year period.
Dosage Forms	**Vials** GARDASIL® is supplied as a carton of: One 0.5 mL single-dose vial **Syringes** GARDASIL® is supplied as a carton of: One 0.5 mL single-dose prefilled Luer Lock syringe, preassembled with an UltraSafe Passive®* delivery system. One needle is provided separately in the package.
Use with concomitant medications**	Results from clinical studies indicate that: • GARDASIL® may be administered concomitantly (at a separate injection site) with hepatitis B vaccine (recombinant) • The use of hormonal contraceptives or immunosuppressants (inhaled, topical, parenteral) did not appear to affect immune responses to GARDASIL®
Contraindications	GARDASIL® is contraindicated in patients who are hypersensitive to the active substances or to any of the excipients of the vaccine. Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL® should not receive further doses.
Warnings and Precautions	As for any vaccine, vaccination with GARDASIL® may not result in protection in all vaccine recipients. This vaccine is not intended to be used for treatment of active genital warts; cervical, vulvar, or vaginal cancers; CIN, VIN, or VaIN. This vaccine will not protect against HPV types not included in this vaccine. Pregnancy should be avoided during the vaccination regimen for GARDASIL®.
Adverse Reactions	The most commonly reported vaccine-related injection-site adverse experiences in clinical trials with GARDASIL® in females (n=5088), aluminum-containing placebo (n=3470) and saline placebo (n=320), respectively, were pain (83.9%, 75.4%, 48.6%), swelling (25.4%, 15.8%, 7.3%), erythema (24.6%, 18.4%, 12.1%) and pruritus (3.1%, 2.8%, 0.6%). The most commonly reported vaccine-related systemic adverse experience in females was fever: 10.3% for GARDASIL® (n=5088) vs 8.6% for aluminum and non-aluminum containing placebo (n=3790).
Storage recommendations	Store refrigerated at 2°C to 8°C. Do not freeze. Protect from light. GARDASIL® should be administered as soon as possible after being removed from refrigeration. When out of refrigeration at room temperature at or below 25°C, administration may be delayed for up to 3 days.
Drug Identification Number (DIN)	02283190
Price per dose	$134.95

* UltraSafe Passive® delivery system is Trademark of Safety Syringes, Inc.

** The safety and immunogenicity of coadministration of GARDASIL® and hepatitis B vaccine (recombinant) (same visit injections at separate sites) were evaluated in a randomized study of 1871 women 16 to 24 years of age at enrollment. Immune response to and safety profile of both hepatitis B vaccine (recombinant) and GARDASIL® were similar whether the vaccines were administered at the same visit or at a different visit.

Please refer to the Product Monograph for more detailed information.

References: 1. Data on file, Merck Frosst Canada Ltd. GARDASIL® - Product Monograph. June 2007. 2. Data on file, Merck & Co., Inc. Clinical overview. November 21, 2005. 3. The European Consortium for Cervical Cancer Education. The Health Professional's HPV Handbook. In: Prendiville W and P Davies, eds. Human Papillomavirus and cervical cancer. New York: Taylor & Francis, 2004. 4. Centres for Disease Control and Prevention. CDC's advisory committee recommends human papillomavirus vaccination, press release, June 2006. Available at: http://www.cdc.gov/od/oc/media/pressrel/r060629.htm

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PAAB

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