

Prescribing Summary Style Guide v1

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1. About This Style Guide

- 1.1 The purpose of this Guide is to provide advertisers and creative agencies with the minimum requirements reflecting PAAB's readability standards introduced on July 1, 2007. It is mostly concerned with the presentation of prescribing information in a layout using common design elements and parameters, such as fonts, columns, margins, gutter widths, hyphenation and justification, leading and tracking, borders and rules, tables and graphic elements. Considering the countless possible combinations of such elements and parameters, this Guide emphasizes *minimum readability requirements*, thus allowing the layout designer plenty of creative flexibility.
- 1.2 While the terminology used in these pages may be partially common to many software programs, this Guide is specifically a *desktop publishing manual* and is not intended for users of word processing, illustration, web design, or photo-editing software.
- 1.3 The examples provided at the end of this Style Guide were thoroughly tested for clarity and readability. Their layouts were developed using current desktop publishing tools. They are easily reproducible using industry-standard software, such as *Adobe InDesign* and *Quark Xpress*, the two commercial layout programs most commonly used by creative agencies since the turn of the millennium. Both programs use common and universal layout design terminology, also used by other commercial or open source desktop publishing programs, so it should not be difficult for users of those other programs to understand and apply the instructions and requirements found herein.
- 1.4 The scope of minimum requirements listed in this Guide and demonstrated in the enclosed examples should be considered as they relate to the layout elements addressed *as a whole*, not partially. For instance, impeccably meeting the typeface use requirements may still result in impeded readability if the requirements for tables or margins are not met. The layout designer may find it best to designate as a template a document that already meets all the requirements, import new prescribing text into it, then organize the document's layout within the requirements' parameters.
- 1.5 The instructions in this Guide are applicable to the *Patient Selection Criteria*, *Safety Information*, and *Administration* sections and subsections of the Prescribing Summary. They are not applicable to the *Study References* or *Supplemental Product Information* sections or subsections. Please consult the PAAB code for specific requirements regarding those two sections.

- 1.6 The main measurement unit used in this Style Guide is the inch. Layout designers using the metric system please note that 1 inch equals 2.54 centimeters.
- 1.7 The current version of this Style Guide (v1) was produced in August of 2008. It was based on field tests conducted by select creative agencies from May to August 2008. Questions, suggestions or concerns about this Guide should be directed to your contact at the Canadian Association of Medical Publishers.

2. Definitions of Layout Elements

- 2.1 **Font:** A font is a file containing a set of scalable glyphs, characters or forms that work together to typeset readable strings of information. Scalable fonts come in three different formats: True Type, Postscript Type 1, and Open Type. The desktop publishing common unit of measure for fonts is the *point*, abbreviated as pt. This unit of measure is sometimes called the *Postscript point*, and has been universally rounded to an even 72 points to the inch. Examples of commonly used fonts are *Helvetica*, *Courier*, *Times Roman*, *Frutiger*, *Univers*, *Garamond* and *Arial*. A collection of fonts that contain the same shapes in different weights and/or stylings is called a *typeface*, or a *font family*. For instance, the fonts Helvetica Roman, Helvetica Bold, and Helvetica Italic are all part of the Helvetica typeface or font family.
- 2.2 **Column:** A column is a vertical block of text positioned on a page. White space, rules, or both usually separate multiple columns on a page.
- 2.3 **Margin:** A margin is the white space that surrounds the content of a page.
- 2.4 **Gutter:** A gutter is the margin (or white space) that separates two columns of text, or two pages combined next to each other (also known as a *2-page spread*).
- 2.5 **Justification:** Also called *full justification*, is the alignment setting of text within a column to align along both the left and right margins. Unjustified text, where it is aligned along the left margin but not the right, is called *ragged right*. Usually the last line of a justified paragraph or column is ragged right, a rule observed by commonly used desktop publishing and layout software. In most cases, justification entails irregular automatic adjustments of the white space between the words and even characters of the justified line.

- 2.6 **Hyphenation:** The act of using a hyphen to indicate a composite word or break a non-composite word into two parts, most commonly at the end of a line in a justified text block. In desktop publishing, the layout software usually does hyphenation automatically. Hyphenation usually counteracts the space irregularities caused by the layout software in justified text, and renders the setting of the text block in a sightlier manner.
- 2.7 **Leading:** The act of adjusting the white space that separates the lines in a text block.
- 2.8 **Tracking:** The act of adjusting the white space that separates the characters in a word, line or a text block. Tracking two individual characters, such as the L and the T (for instance to make the word FELT more sightly) is also known as *kerning*.
- 2.9 **Rules:** Rules are horizontal or vertical lines commonly used to separate layout elements in order to organize the structure of the layout.
- 2.10 **Borders:** Borders are design elements used to frame blocks of graphic visuals or textual information. For the purposes of this Guide, borders are simply rules that frame a column of text, wholly or partially.

3. Columns and Margins

Past and present Prescribing Summary layouts observed commonly use two- or three-column layouts. Unless otherwise specified, the following minimum requirements apply to both layout variations.

- 3.1 The width of a column should be at least 2.5 inches. This minimum measurement accommodates comfortable readability in both two- and three-column environments. In a two-column environment, however, a column width between 3.25 and 3.5 inches is recommended, for visual aesthetic reasons.
- 3.2 The margin of the layout should be at least 0.25 inch. This applies to top, bottom, left and right margins.
- 3.3 The column gutter should be at least 0.25 inch.

4. *Type Use*

The way fonts are handled in the layout greatly determines the quality of the reading experience of the information presented, which in turn determines whether or not the product whose Prescribing Summary is presented becomes favourable with the intended reader. It is very important to make the reading experience of the Prescribing Summary a clear and comfortable one, and fonts are the main elements affecting that experience.

Due to the usually lengthy content of a Prescribing Summary, it is only logical that the fonts most commonly chosen for this task are of the condensed sans serif variety. Examples include Helvetica Condensed, Arial Narrow, Frutiger Condensed, Futura Condensed, and Univers Condensed. These are fine fonts that have proven their worth over decades of use in immersive reading. However, these popular condensed sans serif fonts were constructed to perform within certain parameters of readability. Ignorance or abuse of these parameters may result in a very poor reading experience.

- 4.1 Font weights other than regular, book, medium, normal, semibold, demibold, and bold, should be avoided. Fonts lighter than regular and thicker than bold are meant for display sizes and impede reading at text sizes.
- 4.2 Fonts with widths other than condensed, narrow and normal should be avoided. Fonts narrower than condensed or narrow and wider than normal are meant for display sizes and impede reading at text sizes.
- 4.3 Italic styles may be used in text and headlines, provided that they are not of a weight lighter than regular or thicker than bold, or widths narrower than condensed or wider than normal.
- 4.4 The size of the font used for Prescribing Summary text should be at least 8.5 points, with a minimum leading of 10 points.
- 4.5 If using a **bold** font, the font size should be at least 8 points, with a minimum leading of 8.5 points.
- 4.6 If using mixed font weights in the same paragraph, the text should be set in a font at least 8.5 points in size, and a minimum leading of 10 points.
- 4.7 Text should never be manually stretched or condensed within a layout application.

- 4.8 Text can be tracked as necessary, as long as an average of 25 characters per inch (CPI) is not exceeded when using a condensed or narrow font of a normal, regular or medium weight, an average of 20 characters per inch is not exceeded when using a condensed or narrow width font of a demibold, semibold, or **bold** weight, an average of 15 characters per inch is not exceeded when using a regular width font of normal, regular or medium weight, and an average of 10 characters per inch is not exceeded when using a regular width font of a demibold, semibold, or **bold** weight.

The following table shows these averages, using members the Myriad family of fonts as an example.

FONT USED	AVERAGE CPI
Myriad Condensed	25
Myriad Bold Condensed	20
Myriad (Regular)	15
Myriad Bold	10
Myriad Semibold Condensed	20
Myriad Semibold	10

Characters as defined in this Guide include spaces, numbers, letters, punctuation and common mathematical symbols used in English or French.

- 4.9 Text may be leaded as necessary, as long as it doesn't exceed 8 lines per inch when using a normal, regular or medium weight, or 7 lines per inch when using a demibold, semibold or **bold** weight.
- 4.10 The colour of the Prescribing Summary text, regardless of the font or fonts used, should be at least 90% black, unless the text is knocked out of a black background, in which case the text should be white. The use of black text on a black background, regardless of colour percentages, should be avoided.
- 4.11 When text is knocked out of a black background (e.g. white on black), the font used for the text should be demibold, semibold or **bold**, with a size of at least 8.5 points, with a minimum leading of 9 points. It is not recommended to typeset more than two lines of white text on a black background.

5. Borders and Rules

- 5.1 With the exception of rules used to underline a word or a string of text, any non-border rule used in the Prescribing Summary should be placed at least 0.07 inch from any text or other design elements used in the layout, including other rules.
- 5.2 Rules used to construct borders framing a block of text should be at least 0.07 inch away from the text they frame.
- 5.3 If a non-border rule is used to separate columns, it should be placed in the exact middle of the columns' gutter.

6. Tables

- 6.1 In a three-column layout, the maximum number of table columns should be three. Column widths can be adjusted individually to accommodate content, provided that the total width of the table's columns does not exceed 2.5 inches. See table in the three-column layout example on page 9 of this document.
- 6.2 In a two-column layout, the maximum number of table columns should be five. Column widths can be adjusted individually to accommodate content, provided that the total width of the table's columns does not exceed the width of a main layout text column. See table in the two-column layout on page 8 of this document.
- 6.3 Tables should not travel into the gutter or margin areas of the layout.
- 6.4 The use of fonts within tables should meet the same minimum colour, size, leading and tracking requirements that apply to the rest of the layout.
- 6.5 Table borders should not exceed 2 points in width.
- 6.6 Text within table cells should be at least .1 inch away from all visible borders.
- 6.7 The table itself should be at least .1 inch from the text above it and below it.

7. *Graphic Elements*

- 7.1 Graphic elements, such as company or product brand logos should not affect the flow of the Prescribing Summary text columns. Such elements are best used above or below the entire text of the Prescribing Summary.
- 7.2 If the layout is superimposed on an image (e.g. branded watermark background), the colour of said images should not exceed 15% black. The darker the background, the harder it is to read what is atop it.

 **Prescribing Summary**

 **Patient Selection Criteria**

THERAPEUTIC CLASSIFICATION

Active Immunizing Agent (Suspension for injection)

INDICATIONS AND CLINICAL USE

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 cancer
- Vulvar and vaginal cancers
- Genital warts (condyloma acuminata)
- Cervical adenocarcinoma in situ (AIS)
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Cervical intraepithelial neoplasia (CIN) grade 1

Pediatrics (<9 years of age) /

Geriatrics (>65 years of age)

The safety and efficacy of GARDASIL[®] have not been evaluated in children younger than 9 years and in adults above the age of 26 years.

CONTRAINDICATIONS

- Patients who are hypersensitive to the active substances or to any of the excipients of the vaccine. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING in the Supplemental Product Information.
- Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL[®] should not receive further doses of GARDASIL[®].

SPECIAL POPULATIONS

For use in special populations, see WARNINGS AND PRECAUTIONS, Special Populations.

 **Safety Information**

WARNINGS AND PRECAUTIONS

General

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 diseases that are not caused by HPV. GARDASIL[®] has not been shown to protect against diseases due to non-vaccine HPV types.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.

Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization (see DRUG INTERACTIONS in the Supplemental Product Information). No specific data are available from the use of GARDASIL[®] in these individuals.

This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder only if the benefit clearly outweighs the risk of bleeding following an intramuscular administration in these individuals.

Routine monitoring and Pap test should continue to be performed as indicated, regardless of GARDASIL[®] administration.

Special Populations

The safety, immunogenicity, and efficacy of GARDASIL[®] have not been evaluated in HIV-infected individuals.

Pregnant Women: There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL[®]. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

Merck Frosst Canada Ltd. maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to GARDASIL[®] vaccine. Patients and health-care providers are encouraged to report any exposure to GARDASIL[®] vaccine during pregnancy by calling 1-800-567-2594.

Nursing Women: It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. GARDASIL[®] may be administered to lactating women. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

ADVERSE REACTIONS

(see Supplemental Product Information for full listing)

Adverse Drug Reaction Overview

In clinical trials, GARDASIL[®] was generally well tolerated when compared to placebo (aluminum or non-aluminum containing).

Clinical Trial Adverse Drug Reactions

The most commonly reported vaccine-related injection-site adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 5 days post-vaccination, in females 9 through 26 years of age in clinical trials with GARDASIL[®] (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 experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 15 days post-vaccination, in females in clinical trials with GARDASIL[®] (n=5088) and for aluminum and non-aluminum containing placebo (n=3790), respectively, were fever (10.3%, 8.6%), nausea (4.2%, 4.1%), dizziness (2.8%, 2.6%) and diarrhea (1.2%, 1.5%).

For more details on adverse events reported during clinical trials, see ADVERSE REACTIONS in the Supplemental Product Information.

To report a suspected adverse reaction, please contact Merck Frosst Canada Ltd. by:

Toll-free telephone: 1-800-567-2594

Toll-free fax: 1-877-428-8675

By regular mail: Merck Frosst Canada Ltd., P.O. Box 1005,

Pointe-Claire – Dorval, QC H9R 4P8

 **Administration**

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

GARDASIL[®] should be administered intramuscularly as 3 separate 0.5 mL-doses according to the following schedule:

- First dose: at elected date
- Second dose: 2 months after the first dose
- Third dose: 6 months after the first dose

Individuals are encouraged to adhere to the 0, 2, and 6 months 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.

Administration

GARDASIL[®] should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

GARDASIL[®] must not be injected intravascularly. Subcutaneous and intradermal administration have not been studied, and therefore are not recommended.

The prefilled syringe is for single use only and should not be used for more than one individual. For single-use vials, a separate sterile syringe and needle must be used for each individual.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

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. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Discard the product if particulates are present or if it appears discolored.

Single-dose Vial Use: Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe free of preservatives, antiseptics, and detergents. Once the single-dose vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.

Prefilled Syringe Use: Inject the entire contents of the syringe.

For instructions for using the prefilled single-dose syringes preassembled with needle guard (safety) device, see DOSING AND ADMINISTRATION, Administration in the product monograph.

STORAGE AND STABILITY

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.

	CELEBREX 100-200 mg BID and 200 mg QD (n=4,146)	Placebo (n=1,864)	Naproxen 500 mg BID (n=1,366)	Ibuprofen 800 mg TID (n=387)
Abdominal pain	4.1%	2.8%	7.7%	9.0%
Diarrhea	5.6%	3.8%	5.3%	9.3%
Dyspepsia	8.8%	6.2%	12.2%	10.9%
Flatulence	2.2%	1.0%	3.6%	4.1%
Nausea	3.5%	4.2%	6.0%	3.4%

Table borrowed from a Celebrex[®] Prescribing Summary page for illustrative purposes.



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

Prescribing Summary

Patient Selection Criteria

THERAPEUTIC CLASSIFICATION

Active Immunizing Agent (Suspension for injection)

INDICATIONS AND CLINICAL USE

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 cancer
- Vulvar and vaginal cancers
- Genital warts (condyloma acuminata)
- Cervical adenocarcinoma in situ (AIS)
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (ValN) grade 2 and grade 3
- Cervical intraepithelial neoplasia (CIN) grade 1

Pediatrics (<9 years of age) / Geriatrics (>65 years of age)

The safety and efficacy of GARDASIL® have not been evaluated in children younger than 9 years and in adults above the age of 26 years.

CONTRAINDICATIONS

- Patients who are hypersensitive to the active substances or to any of the excipients of the vaccine. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING in the Supplemental Product Information.
- Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL® should not receive further doses of GARDASIL®.

SPECIAL POPULATIONS

For use in special populations, see WARNINGS AND PRECAUTIONS, Special Populations.

Safety Information

WARNINGS AND PRECAUTIONS

General

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 ValN.

This vaccine will not protect against diseases that are not caused by HPV. GARDASIL® has not been shown to protect against diseases due to non-vaccine HPV types.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.

Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization (see DRUG INTERACTIONS in the Supplemental Product Information). No specific data are available from the use of GARDASIL® in these individuals.

This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder only if the benefit clearly outweighs the risk of bleeding following an intramuscular administration in these individuals.

GARDASIL® is a Registered Trademark of Merck & Co., Inc. Used under license.

Routine monitoring and Pap test should continue to be performed as indicated, regardless of GARDASIL® administration.

Special Populations

The safety, immunogenicity, and efficacy of GARDASIL® have not been evaluated in HIV-infected individuals.

Pregnant Women: There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL®. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

Merck Frosst Canada Ltd. maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to GARDASIL® vaccine. Patients and health-care providers are encouraged to report any exposure to GARDASIL® vaccine during pregnancy by calling 1-800-567-2594.

Nursing Women: It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. GARDASIL® may be administered to lactating women. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

ADVERSE REACTIONS

(see Supplemental Product Information for full listing)

Adverse Drug Reaction Overview

In clinical trials, GARDASIL® was generally well tolerated when compared to placebo (aluminum or non-aluminum containing).

Clinical Trial Adverse Drug Reactions

The most commonly reported vaccine-related injection-site adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 15 days post-vaccination, in females 9 through 26 years of age in clinical trials with GARDASIL® (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 experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 15 days post-vaccination, in females in clinical trials with GARDASIL® (n=5088) and for aluminum and non-aluminum containing placebo (n=3790), respectively, were fever (10.3%, 8.6%), nausea (4.2%, 4.1%), dizziness (2.8%, 2.6%) and diarrhea (1.2%, 1.5%).

For more details on adverse events reported during clinical trials, see ADVERSE REACTIONS in the Supplemental Product Information.

To report a suspected adverse reaction, please contact Merck Frosst Canada Ltd. by:

Toll-free telephone: 1-800-567-2594

Toll-free fax: 1-877-428-8675

By regular mail: Merck Frosst Canada Ltd., P.O. Box 1005, Pointe-Claire – Dorval, QC H9R 4P8

Administration

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

GARDASIL® should be administered intramuscularly as 3 separate 0.5 mL-doses according to the following schedule:

- First dose: at elected date
- Second dose: 2 months after the first dose
- Third dose: 6 months after the first dose

Individuals are encouraged to adhere to the 0, 2, and 6 months 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.

Administration

GARDASIL® should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

GARDASIL® must not be injected intravascularly. Subcutaneous and intradermal administration have not been studied, and therefore are not recommended.

The prefilled syringe is for single use only and should not be used for more than one individual. For single-use vials, a separate sterile syringe and needle must be used

for each individual.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

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. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Discard the product if particulates are present or if it appears discolored.

Single-dose Vial Use: Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe free of preservatives, antiseptics, and detergents. Once the single-dose vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.

Prefilled Syringe Use: Inject the entire contents of the syringe.

For instructions for using the prefilled single-dose syringes preassembled with needle guard (safety) device, see DOSING AND ADMINISTRATION, Administration in the product monograph.

STORAGE AND STABILITY

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.

All Patients	Celecoxib 400 mg BID (n=3,987)	Diclofenac 75 mg BID (n=1,996)
All withdrawals	22.4	26.5 [†]
Withdrawals for GI Symptoms	12.2	16.6 [†]
Serious adverse events	6.8	5.6
Myocardial infarction (fatal and non-fatal)	0.5	0.2
Deep Vein Thrombosis	0.2	0.3
Cardiac Failure	0.2	0.1
Unstable Angina	0.2	0.2
Cerebrovascular disorder	0.1	0.3
Patients Without ASA	(n=3,105)	(n=1,551)
All withdrawals	21.2	25.4 [†]
Withdrawals for GI Symptoms	11.5	15.4 [†]
Serious adverse events	5.0	4.2
Myocardial infarction (fatal and non-fatal)	0.2	0.1

Table borrowed from a Celebrex® Prescribing Summary page for illustrative purposes.