HOW TO READ A

Vaccine Monograph

What is a Product Monograph?

A product monograph, often called a package insert, is a document that provides detailed scientific information about a drug product, including its properties, uses, dosage, and safety information, without any promotional content. It is essential for ensuring the safe and effective use of the drug and is required for marketing the product in Canada.

Opening a vaccine product monograph for the very first time can be overwhelming and seemingly impossible to read. The fine print and foreign medical terminology can make you feel that it's better left to a doctor or nurse to explain how the vaccine works. However, every product monograph is written in a standardized format with 20 sections. Once you understand what each section covers, navigating any vaccine monograph becomes easy.

The vaccine product monograph contains important information, such as:

- What are the ingredients?
- What are the benefits and risks of the vaccine?
- What are the known short-term and long-term harms of the vaccine?
- How often do vaccine injuries occur?
- Does the vaccine prevent transmission or infection?
- How was safety testing conducted, and for how long?

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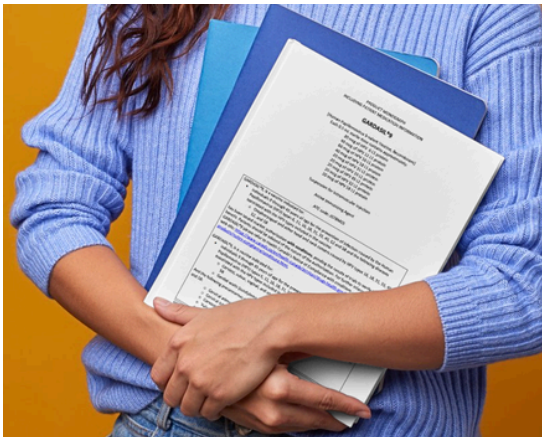
Section 1: Indications in the monograph explains who the vaccine is intended for and the conditions or diseases it is approved to prevent or treat. This section lists the specific uses based on age, gender, and disease type.



Section 2: Dosage and Administration provides detailed instructions for healthcare providers on how to properly administer the vaccine (e.g., whether the vaccine is given intramuscularly, subcutaneously, or orally).

Section 3: Dosage Forms and Strengths provides a brief description of the vaccine and the amount to be given. It explains the form of the vaccine (e.g., suspension for injection), the strength or concentration per dose, and, in some cases, the presentation (e.g., prefilled syringe).

Section 4: Contraindications clearly states the **situations in which the vaccine must not be given.** Pay particular attention to this section, and if you fall into any of the contradictions, such as:

- Having had a known severe allergic reaction (e.g., anaphylaxis) to any ingredient of the vaccine or from a previous dose.
- Having specific medical conditions or circumstances that make vaccination unsafe.

Section 5: Warnings and Precautions provides important information about **potential risks, conditions that require caution, and situations where monitoring** may be needed before or after administering the vaccine. Typically included are precautions for specific populations, risk of allergic reactions, possible interactions with medical conditions, and guidance on monitoring.

For example, in the meningococcal vaccine insert, MENVEO, it states, "As a precautionary measure, Epinephrine Hydrochloride Solution and other appropriate agents and equipment must be immediately available in case anaphylactic or serious allergic reactions."

Section 6: Adverse Reactions lays out the possible side effects or adverse reactions that can occur after receiving the vaccine. This is a very important section that should not be missed, as it teaches you how to spot a vaccine reaction.

- **Common Adverse Reactions:** mild, temporary symptoms such as pain or swelling at the injection site, fever, fatigue, headache, or muscle pain.
- **Serious Adverse Reactions:** adverse reactions that require medical attention or hospitalization, such as allergic reactions or anaphylaxis.
- **Frequency of Adverse Reactions:** categorizes reactions by their frequency, such as common, uncommon, or rare, providing percentages or general estimates based on clinical studies or post-marketing data.
- **Post-Market Surveillance Data:** adverse events reported after the vaccine has been on the market, including data collected from the general population.

Section 7: Drug Interactions provides information on how the vaccine may interact with other medications and vaccines, whether it should be administered at separate injection sites, and how certain drugs (e.g., immunosuppressants) may affect the vaccine's effectiveness or increase the risk of side effects.

Section 8: Use in Specific Populations typically covers information on the safety of the vaccine during pregnancy and lactation (breastfeeding); provides specific information regarding its use in children, geriatric populations; and outlines special considerations for individuals with weakened immune systems, including whether the vaccine is appropriate or if its efficacy may be reduced.

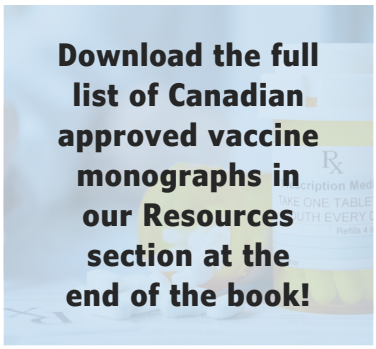
Section 9: Drug Abuse and Dependence more often included in drug package inserts; in vaccine inserts, usually marked as "not applicable."

Section 10: Overdosage discusses what is known about the effects of receiving more than the recommended dose of the vaccine. However, for the majority of vaccines, this section is brief or marked as "not applicable."

Section 11: Description provides the technical description of the vaccine. For many people, this is the first place you want to check, as it includes the vaccine's ingredient list.

Here is a basic breakdown of the section:

- **Vaccine Composition –** type of vaccine (e.g., mRNA, live attenuated), active ingredients, excipients/inactive ingredients (stabilizers, preservatives, adjuvants, buffers, or salts).
- **Formulation and Presentation –** dosage form, how the vaccine is supplied, and the volume per dose (e.g., 0.5 mL).
- **Route of Administration –** how the vaccine is given.



- **Description of the Vaccine's Physical Appearance –** what it looks like.
- **Manufacturing Source –** cell lines or organisms used in manufacturing and the expression systems for recombinant vaccines.
- **Other Ingredients or Materials –** trace components from manufacturing (e.g., antibiotics, egg protein), and residual solvents or process-related impurities. It's important to note that while the package insert may state an ingredient is present in *trace amounts*, it is still in the vaccine and may be harmful.

Section 12: Clinical Pharmacology explains how the vaccine works in the body—its mechanism of action, the effects on the immune system, and how it's expected to protect against the disease or illness.

Section 13: Nonclinical Toxicology shows the findings from animal studies that assess the vaccine's safety before going to human trials. However, there are often no animal studies conducted. A disclaimer is written in this section that states the following: No studies have been conducted in animals to evaluate whether the vaccine causes cancer, genetic mutations, or fertility problems.

Section 14: Clinical Studies presents the data from human clinical trials, which includes:

- **Study design details** – how the trials were conducted, including population size, age groups, dosing schedules, and control groups.
- **Efficacy results** – shows how well the vaccine prevented infection or disease (e.g., % reduction in HPV-related lesions or COVID-19 cases).
- **Subgroup analyses** – results by age, sex, or risk group (e.g., immunocompromised individuals).

Vaccine safety studies often only include healthy subjects and do not include children, pregnant women, frail elderly, or immunocompromised subjects. However, vaccines are frequently recommended for these groups.

Section 15: References for the data in the insert, linking to clinical studies and scientific literature used to substantiate the vaccine's safety and effectiveness.

Section 16: How Supplied/Storage and Handling outlines how the vaccine is packaged, stored, and handled, including temperature requirements and preparation steps to ensure safety for healthcare professionals who administer the vaccine.

Section 17: Patient Counselling Information provides points to ensure that patients are well-informed about the vaccine's purpose, side effects, precautions or contraindications, and emphasizes the importance of completing the full vaccination series if more than one dose is required. A patient should be presented with not just this section or the patient information sheet, but the entire package insert.

Section 18: Information for Healthcare Providers including administration, monitoring, and management of patients receiving the vaccine.

Section 19: Post-marketing Experience details the adverse events that have been reported after the vaccine was released to market and used in the general population. This section is very important because it includes real-world data. Many clinical trials only monitor for side effects for a mere 21 days, sometimes less. [81] For example, in Merck's clinical trial for the Hepatitis B vaccine, participants were monitored for a total of 5 days. Short follow-up periods are insufficient to capture moderate and long-term adverse effects.

Section 20: Regulatory Approval shows the regulatory background for the vaccine, explaining its approval status, conditions of approval, and the clinical data used to support its safety and efficacy.

> *The question is not whether vaccines are good or bad, but whether every single vaccine is truly necessary and as safe as it can possibly be. That requires rigorous, transparent, and continuous scrutiny.*
>
> **ANDREW J. WAKEFIELD**
> Author of "Callous Disregard: Autism and Vaccines: The Truth Behind a Tragedy"

A 2010 study conducted for the U.S. Department of Health and Human Services at Harvard Pilgrim Hospital concluded that **fewer than 1% of vaccine adverse events are reported.**

This means that the amount of vaccine injury could be more than 100 times the reported rate. [80]