

Biologics and Biosimilars for the Treatment of Inflammatory Arthritis



What is inflammatory arthritis?



What treatments are available for inflammatory arthritis?



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What is inflammatory arthritis?

Inflammatory arthritis is a group of conditions where the body's defense system begins to attack healthy tissues, particularly around the joints, causing *inflammation*—redness and swelling which causes pain and, when in the joints, can also cause stiffness. Left untreated, inflammation can lead to significant and often irreparable damage to the affected areas, resulting in loss of function and disability. Early treatment aimed at reducing inflammation is important to prevent this damage.

Patients should see their doctor as soon as possible if they begin noticing symptoms of arthritis. Some of the most common symptoms include stiffness in one or more joints along with swelling, pain and/or tenderness. By identifying arthritis early, treatment can be started to slow the progression of the disease and prevent further damage to the joints. It is important to start treatment as early as possible because once a joint is damaged, the damage cannot be reversed.

There are over 100 forms of inflammatory arthritis and the causes are numerous, such as infections, trauma, and autoimmune reactions where the immune system attacks the body. The most common inflammatory forms of arthritis in adults are [rheumatoid arthritis](#), [ankylosing spondylitis](#) and [psoriatic arthritis](#). Inflammatory arthritis also affects children.

To learn more about specific types of arthritis, visit: [Arthritis Types A-Z](#).

What treatments are available for inflammatory arthritis?

There are many different types of inflammatory arthritis and many different types of treatments—both medical (such as drugs and surgery) and non-medical (such as physical activity). For inflammatory arthritis, traditional medical treatments include disease-modifying anti-rheumatic drugs (DMARDs) and non-steroidal anti-inflammatory drugs (NSAIDs), but in recent years, advanced medications called **biologics** have been introduced that offer powerful treatment options for patients when other treatments have failed to work.

Disease-modifying antirheumatic drugs (DMARDs) such as methotrexate target the body's overactive immune system and stop it from attacking healthy tissues. These medications do not provide immediate pain relief since they work over weeks to months to slow the inflammatory processes in the body. When used consistently as prescribed by your doctor, they can protect joints and other tissues from further damage and prevent progression of the disease.

Non-steroidal anti-inflammatory drugs (NSAIDs) (eg. Diclofenac, ibuprofen, naproxen) provide quick-acting pain relief by suppressing the body's inflammatory response. Some types of NSAIDs may be available over-the-counter without a prescription. However, these medications can interact with other medications and may not be the best choice for some people. Always check with your pharmacist or doctor before starting an NSAID.

Biologics are complex, biological compounds made with living cells. These medications target problem proteins in the body to calm the immune system and prevent further damage to healthy tissues and joints.

What are biologics?

Biologics are a class of drugs that were first launched in the early 1990s. They can be prescribed instead of (or in addition to) more common medical treatments.

Biologics are large, complex biological compounds that are made from living cells—bacterial or yeast cells or cells obtained from plants or animals—rather than being manufactured chemically like most other drugs. For people coping with inflammatory arthritis, biologics work by calming the immune system and thereby reducing pain, stiffness and other symptoms.

Most biologics must be injected under the skin (subcutaneously) or administered by intravenous infusion since they are broken down by the process of digestion when taken by mouth.

Biological products provide additional options for the treatment of arthritis. These therapies are more precise in targeting the body's immune system to prevent and improve symptoms as well as slow progression of the condition.

More information about medication for arthritis, including biologics is available in our [Medication Reference Guide](#).

What are biosimilars?

Biosimilars are biologics that are produced by manufacturers after the patent on an originator biologic expires. Because biologics are very complex molecules produced using living cells it is not possible to duplicate them exactly. For this reason, different versions of the same biologic are called **biosimilars**, because they are **very similar** (but not identical) to the original biologic. More information about biosimilars is available here: [Health Canada](#).

Are biosimilars the same as generic drugs?

The short answer is no, biosimilars are not the same as generic drugs.

While innovator biologics and biosimilars are very similar to one another, we cannot say they are exactly the same. This is because of the inherent variability of complex biological compounds. You can think of biologics like apples growing on a tree. There is inherent variability in each apple, even those that grow on the same tree. This is because apples are complex with many factors affecting their growth. Similarly, batches of biologics made will vary slightly from batch to batch with the same manufacturer. However, you can think of regular chemical drugs such as aspirin (acetylsalicylic acid or ASA) to be like coins. When coins are produced, each one is identical to the rest because the manufacturing is reproducible and there is no inherent variability in the product. They remain identical even when produced in a different year.

A generic drug is chemically manufactured to be an exact copy of the original drug, because the active ingredients are relatively easy to duplicate. For example, acetaminophen, a common pain reliever, is the same active chemical ingredient whether you buy the brand name or a generic version. The medicinal ingredients will be identical, but some non-medicinal ingredients such as those used to make the color of the tablet and its coating, may be different.

Biosimilars are highly similar to the originator and produced with different recipes. Due to the complexity and specialized processes involved to make them, biosimilars are only highly similar – not identical to the originator. The same would be true from one batch of originator biologics to the other – that batch would have a slight variability compared to the starting batch. These differences do not impact the safety or efficacy of the drugs. Any significant changes to the recipe or manufacturing process requires approval by Health Canada and batch to batch variations do not require approval if variations are within the limits set.

Biosimilars are also different from generics when it comes to the studies required for Health Canada approval.

Since generic drugs are small molecules with active ingredients that are easy to replicate, generic drugs only need to show bioequivalence to the brand name product to demonstrate safety and efficacy. To be considered bioequivalent, the generic drug must achieve a certain level in the blood and act the same way in the body as the brand name drug. Typically, these studies are done in less than 50 healthy volunteers to demonstrate bioequivalence for Health Canada approval. Clinical trials in people with the condition are not required for a generic version.

Since biosimilars are larger and more complex therapies that are created with living cells, biosimilars must undergo structural and functional studies as well as human clinical trials to demonstrate comparable quality, safety, and efficacy to the reference biologic.

Whatever drug you are getting, whether it is a generic drug or a biosimilar, you can be confident knowing that Health Canada regulations ensure the drugs you receive are safe, effective, and of high quality.

Are biologics/biosimilars safe?

Health Canada is responsible for making sure that all new drugs, including biologics and biosimilars, are safe, effective and of high quality.

Health Canada evaluates all the information provided to confirm that the biosimilar and the original biologic drug are similar and that there are no clinically meaningful differences in safety and efficacy between them.

How do biologics/biosimilars work?

Biologics are a class of drugs designed to treat various conditions, including inflammatory autoimmune conditions. Biologics work to reduce the inflammation and can help to prevent further damage to the joints.

In some people with arthritis, high levels of certain proteins may be present in the blood and joints leading to inflammation (and therefore pain, swelling and stiffness). Biologics and biosimilars work to calm the body's overactive immune system by blocking these proteins and their ability to cause inflammation.

An informative video on inflammatory arthritis and different treatment options, including biosimilars is available here: [Inflammatory Arthritis Medications Simplified](#) Your doctor may suggest that your biologic be taken in combination with other drugs to increase the chance of successful treatment of your arthritis.

If I am considering biologics/biosimilars, what do I need to know?

What are my options?

There are different biologics that could be offered to you to treat your inflammatory arthritis. One could be more appropriate for you or your type of arthritis. Make sure you discuss with your doctor the pros and cons of the different treatments available.

You might want to consider:

1. how the drug is given (by mouth, by injection, or by infusion)
2. potential side effects or drug interactions
3. the cost of the drug and your coverage
4. how often you will have to take the drug

How is the drug given?

Generally, biologics need to be either injected or given by infusion (intravenous or IV). You can inject the biologic yourself, but infusions must be done in a clinic, a process that may take several hours to complete. If you will be injecting the drug yourself, you may be able to choose either a pre-filled syringe or an autoinjector pen. An autoinjector injects without the need for you to push on the syringe plunger. Each dosage form may be slightly different. For example, the size, shape, color, and injecting mechanism can vary. You can talk with your doctor or pharmacist to decide what option is best for you.

If you are getting an infusion, you may have a choice of what infusion clinic to go to. Talk to your doctor about what infusion clinics can infuse your medication, where they are located, and what other services they might include. The patient support program associated with the medication you have been prescribed can also help in identifying convenient locations for administering your treatment.

Will biologics work for me?

As with all treatments, people can react differently to the same medication. Some people find that biologics act very quickly (within days) to reduce their symptoms while others find that it takes longer (weeks or even months). Some people find that biologics help to reduce their symptoms while others find that they become nearly symptom-free. For others, biologics may not work at all.

When on biologics, you should reach out to your doctor if:

- you have a fever;
- you have an infection;
- you need to take an antibiotic;
- you are considering surgery; or
- you want to get pregnant.

How much do they cost?

Biologics are expensive drugs—whether you are paying for them yourself, or through a provincial or private drug plan. Each originator biologic and biosimilar product has an associated patient support program which helps patients obtain any drug coverage available to them to help cover the cost of the biologic. Your pharmacist can also help you understand what drug coverage is available to you.

Biosimilars are usually less expensive than the originator biologic. This is in part because it is less expensive for a pharmaceutical manufacturer to create a copy of an effective drug than to develop an entirely new drug. These reduced costs can help more patients gain access to these life-changing

therapies and can allow government to allocate cost-savings towards funding other products and programs that will improve the health of Canadians.

What about fighting infections?

Biologics are designed to calm the immune system because autoimmune diseases are caused by the body's immune system attacking its own healthy tissues. Biologics help prevent your immune system from attacking healthy tissues, but they can also make it harder for your body to attack foreign bacteria and viruses that cause infection. Therefore, when you are taking a biologic, it can be harder for your body to fight infections. You will need to be very careful to prevent infections when you are on a biologic. Wash your hands frequently and try to avoid contact with sick people who may have active infections. Also, before you start taking a biologic, make sure that your vaccinations are up to date and that you have seen your dentist to be sure you have no cavities or gum disease. It is best to get your necessary vaccinations before you start a biologic medication. Your physician or pharmacist can help you identify which vaccinations are right for you.

If you have to take antibiotics for an infection, tell your doctor so that they can assess whether or not to continue your biologic at the same time. In some cases, your doctor may advise you to temporarily stop taking your biologic until the infection is resolved. Your doctor will let you know when to resume your biologic treatment.

Transitioning to a biosimilar

Are biosimilars as effective as the originator biologic?

Yes. Health Canada considers approved biosimilars to be the same quality, efficacy and safety as originator biologics. According to [Health Canada](#), "Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications. Our rigorous standards for authorization mean that you can have the same confidence in the quality, efficacy and safety of a biosimilar as in any other biologic drug."

Will transitioning my originator biologic to a biosimilar cause a health problem?

You should not experience any negative effects from a transition. According to Health Canada: "No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication."

How long have biosimilars been in Canada?

Biosimilars have been approved for use in Canada since 2009, and for treating inflammatory arthritis since 2014. They have been used to treat inflammatory arthritis in Europe for over a decade without producing any unexpected safety concerns.

For more information about transitioning from an originator biologic to a biosimilar, visit our flourish article on [Biologics and Biosimilars](#).

The Nocebo Effect

What is the Nocebo Effect?

The nocebo effect is when a patient develops side effects or symptoms just because they believe they will occur or have heard negative information which affects their perception. Studies have shown that sometimes people who anticipate negative side effects from a new medication may be more likely to experience them. Information you find on the internet may not be accurate and you must ensure the information you access is from a reliable and reputable source. Licensed healthcare professionals are your best source of information and they can individualize the information to you.

Why does it occur?

The nocebo effect demonstrates the impact that negative thinking can have on our bodies. It can occur when patients get misinformation or see the risk of side effects as far greater than they actually are. Reading or hearing about misinformation can cause you to perceive negative effects from a treatment, even when they do not truly exist, especially if the information you hear is biased or unbalanced.

Why is it important?

The nocebo effect can make otherwise excellent treatments intolerable for patients. Measures should be taken to avoid the nocebo effect in order to ensure the best chance of success with a new treatment.

What can I do about it?

It is important to make sure that you have a clear understanding of any treatment proposed. Your doctor or pharmacist can provide you with additional information about a particular treatment and individualize the information for you. If you have concerns about a medication, talk to your doctor or pharmacist before starting it. They can help you understand the benefit of your medication which greatly outweighs the risk of side effects. It may help for you to understand your options and what is available to you so you may participate in a shared decision-making process about your treatment. Make sure you get the facts before starting a new treatment so that misconceptions don't interfere with how you perceive its efficacy and safety.

How do I talk about different treatment options with my doctor?

There are many types of arthritis and many different treatments: it can feel a little overwhelming. But it is important that you are involved in the choice of your treatments, and to be involved you need to know as much as possible about your condition and your treatment options.

It should not be difficult to discuss your concerns and questions with your doctor, but doctors are busy and may not always have the time to explain things thoroughly. You may also find it difficult to understand the medical terms that they use. To make the most of your time with your doctor, try to do some reading about your condition and treatment options before your appointment.

You can also talk with your local pharmacist to better understand what drug treatment options are available to you. Your pharmacist can help to explain the benefits and side effects of various treatment

options as well as assess for drug interactions. They can also help to explain the cost of different medications and identify what coverage is available for you.

Write down any questions you have before seeing your doctor or pharmacist so you remember what to ask. During the appointment, write down your doctor's answers so you can look at them again later. Better yet, consider bringing someone with you to your appointment to take notes for you.

Here are some things that you should consider and discuss with your doctor or pharmacist:

- What might you expect from a biologic treatment?
- Does the treatment work with your lifestyle? For example, will it be hard for you to get time off work to go to an infusion clinic regularly? Are you afraid of giving yourself a needle?
- What are the side effects of this treatment?
- Does this treatment affect other medications you are taking?
- What options are available for administration such as oral, subcutaneous injection and intravenous injection?
- What do you need to think about if you are travelling? Do you need a special "travel letter"? How do you keep your biologics safe while you travel?
- Are there any special considerations if you have other health issues? Are there any special considerations if you are pregnant or want to become pregnant?
- Are there special considerations if you are self-employed? Is there someone who can help you get reimbursed for the cost of your biologics?
- Does the biologic your doctor has recommended have a patient support program? What services does the support program offer? Are there any other supports available to you for this treatment?
- If you are considering switching from an originator biologic to its biosimilar, here are some questions you should discuss with your doctor:
 - What is the reason for switching?
 - Are there any implications if I continue on my current biologic?
 - If your biosimilar is delivered by infusion, will you need to go to a different infusion centre from where you go now?
 - If your biosimilar is delivered by injection, will the device work the same way? Will you need additional training?
 - Is the patient support program different from the one you are currently on? If so, how?
 - With your medical history, are there any reasons why you should or should not change to the biosimilar?
 - While your response is expected to be the same as that of the originator biologic, is there anything that you may need to monitor when switching?

| [A printable version of these questions are available here](#) [PDF]

Work with your doctor to make informed and shared decisions about your treatment options, including biologics/biosimilars.

More information about how to speak with your doctor is available here:
[You and Your Healthcare Provider: A Guide to Effective Conversations](#)

Practical things you should do when on biologics/biosimilars:

- Take your medications as directed by your doctor.
- Do blood work as requested by your doctor.
- Discuss any vaccines you might need with your doctor. It is best to do this before starting a biologic because some biologics can affect your body's response to vaccines, and most can affect your ability to fight infections though vaccines can help.
- Consult your doctor about any planned surgery.
- Make an appointment with your doctor before the renewal date of your medication.
- Carry a list of all your medications at all times. You can get a list of your medications from your pharmacist.
- Carry all of your doctors' names and contact information (general practitioner and specialist) with you at all times.
- Complete the medical information emergency file on your mobile phone.
- Store your medications as directed. Keep your medications out of reach of children. Some medications must be stored at fridge temperatures and have only a short expiry time when stored at room temperature.
- If required, ensure you have a proper travel letter when you are travelling with your medication.
- Be fully aware of all the resources the Arthritis Society offers to help you with your disease.

Biologics that require special storage conditions

Some biologics must always be refrigerated and stored between 2 and 8 degrees Celsius until they are used. This is because warmer temperatures can cause proteins in the medication to break down and become inactivated. If this happens, the medication may not work.

Your healthcare providers take special care to ensure that the cold chain is not broken, and your medication stays between 2 and 8 degrees Celsius at all times. If you are picking up your medication from the pharmacy, you will be responsible for storing your medication properly until it is used.

Ask your pharmacist for a cool carrier if you are not able to put the drug in your refrigerator right away. When you get home, put the drug in your refrigerator immediately. Store the medication in the big part of your fridge and not in the door as the temperature tends to fluctuate more in that area.

If at any point you are concerned that your medication may have dropped below the designated temperature, call your pharmacist. They will be able to advise you on whether your medication is still safe to use.

See the Arthritis Society's [Medication Reference Guide](#) to check if your medication requires special storage conditions.

Patient Support Programs (PSPs)

What are they and how can they help?

Your biologic or biosimilar product may have an associated patient support program which can help you get access to medications and figure out how to pay for it. They can also help you navigate the healthcare

system from diagnosis to starting treatment. They might help by connecting you with a pharmacy or infusion clinic if the medication must be infused.

The patient support program may be able to provide self-injection training if you need it or arrange for you to be trained.

Often patient support programs will help to coordinate the delivery of your medication from the pharmacy to the infusion clinic so patients just have to show up for their appointment and receive their infusion without worrying about obtaining the medication themselves beforehand. Patient support programs may also help patients obtain any drug coverage available to them to help cover for the cost of the biologic. Some may be able to provide financial assistance if you are in financial hardship.

What can I expect from them?

When you are started on a biologic that has an associated patient support program, your doctor will fill out a form to enrol you in the program. You receive a call from the patient support program with more information. Sometimes they may ask for your health information over the phone in order to coordinate your care and help you navigate the healthcare system.

What are their limitations?

Patient support programs are funded by pharmaceutical manufacturers to help patients get access to their product. The staff from the patient support program will be able to provide you with information about that drug product but will not be able to give you medical advice or talk about other drugs you may be on. They are specifically focused on the product they are associated with. You should speak with your doctor or pharmacist if you have questions about medical or medication issues.

Different biologics will have a different patient support program. This means that if you are switching to a different biologic, you may be switching to a different patient support program as well. You can ask your doctor about what to expect when switching to a new drug. Usually, the new patient support program will help to make your transition as seamless as possible.

Where can I get more information?

Arthritis is a complex condition, and there are many types, each with its own symptoms and possible medical and non-medical treatments. More information is available here:

- [Biologics and Biosimilars - Other Resources](#)
- [Health Canada](#)

What does the Arthritis Society do?

The Arthritis Society's vision is to live in a world where people can be free from the devastating effects that arthritis can have on lives. To that end, we invest in cutting-edge research, proactive advocacy and innovative solutions that will deliver better health outcomes and an improved quality of life for people affected by arthritis.

The [Arthritis Society](#) provides information and education to people coping with arthritis so that they, together with their doctors, can make the most appropriate and informed choices for their needs.