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# BIOLOGIC AND BIOSIMILAR MEDICATIONS

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IN THE TREATMENT OF IBD



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# BIOLOGIC AND BIOSIMILAR MEDICATIONS IN THE TREATMENT OF IBD



Crohn's disease and ulcerative colitis are the two main forms of inflammatory bowel disease (IBD). They are also referred to as immune-mediated or auto-immune diseases which can result in the inflammation of the gut (intestines) and outside the gut (extra-intestinal). The symptoms associated with ongoing inflammation may result in severe abdominal pain, diarrhea, vomiting, fatigue, weight loss, osteoporosis, and growth failure in children.

One of the exciting developments arising from IBD research is in the field of biologic therapy. Biologic medications are engineered to target specific activity in the immune system to treat inflammation in some patients with Crohn's disease or ulcerative colitis.

# INFLAMMATION AND IMMUNITY IN CROHN'S AND COLITIS

Inflammation is the body's normal and natural response to things like injury, infection (e.g., bacteria, viruses), certain types of stress, and pain. Any of these triggers will set off activity at the injured site, as well as in your vascular system (veins, arteries, blood flow) and your immune system. When inflammation occurs in a patient with Crohn's disease or ulcerative colitis, cells in the digestive system or gastrointestinal tract release chemicals which act like a 911 emergency call. These signals help the body deal with the injury or infection at the site. As a result, there will be swelling in the area, which may result in pain and heat; also referred to as inflammation or a flare.

Inflammation in the short-term is essential for repairing the injured area in the gut, protecting it against further injury, and healing it. For reasons not fully understood, sometimes the immune system does not switch off after the initial response and begins to damage healthy tissue and is called immune-mediated disease. Crohn's disease, ulcerative colitis, rheumatoid arthritis and multiple sclerosis are examples of immune-mediated or autoimmune diseases.

Crohn's disease and ulcerative colitis can bring on symptoms of severe abdominal pain, diarrhea, nausea, vomiting and fatigue. They are signs of an immune system that is not working properly (i.e. inflammation does not shut off in the gastrointestinal tract and its inner lining).



# WHAT ARE BIOLOGICS?

A biologic is a drug derived from living cells. Vaccines, insulin and monoclonal antibodies are all examples of biologics. They often have large and complex molecular structures. Due to the complexity in manufacturing biologics from living cells, they tend to be higher in cost and are relatively difficult to replicate precisely in comparison to conventional (small molecule) drugs, which are composed of simple chemical structures. Biologics are generally administered by injection, subcutaneously or intravenously.

Biologic medications currently approved for treatment of Crohn's disease and ulcerative colitis in Canada have been developed to target specific molecules within the inflammatory processes in order to control inflammation. They may target different parts of the immune response to control inflammation, such as altering some of the inflammatory signals or stopping some cells from travelling to the areas of inflammation in the gut, thereby allowing the gut to heal.

If you have moderate to severe IBD, you should discuss with your physician if and which biologic therapy is most appropriate for you. It is better to start off with the most appropriate therapy prescribed by your doctor. The decision to switch between biologics should be made by the treating physician in consultation with you.

Manufacturers of biologics tend to offer a wide variety of support to patients, including coordination of injection/infusion services and investigation of reimbursement options.

# WHAT ARE BIOSIMILARS?

As patent protections for originator biologics expire in Canada, biosimilars (also known as subsequent entry biologics or SEBs), are becoming available in the treatment of IBD. While not identical to the originating biologic, biosimilars have structure and function that are highly similar to reference biologics, with the expectation that this translates to similar efficacy and safety.

It is important to note that biosimilars are not considered generic biologics. However, like generic medications, biosimilars can be a cost effective treatment for IBD.

Patients should be aware of the risks and benefits of switching their treatment from one biologic to to another. The best course of action is to discuss with your doctor to determine what treatment is right for you.

## Biologic and biosimilar drugs in Canada for treatment of IBD

Drug Name (Brand)	Type*	Treatment	Administered
Adalimumab (Humira®)	Anti-TNF	Treatment for moderate to severe Crohn's disease (adult and pediatric) and colitis (adult). It is used for patient who have not responded well to conventional therapies, or who have lost response to other biologics.	By subcutaneous injection (SC)
Infliximab (Remicade®, Inflectra®, Renflexis®)	Anti-TNF	Treatment for moderate to severe Crohn's disease, fistulizing Crohn's and ulcerative colitis (adults and pediatric). It is used for patient who have not responses well to conventional therapies.	By intravenous (IV)
Golimumab (Simponi®)	Anti-TNF	Treatment for moderate to severe colitis in adults. It is used when conventional colitis medicines have not worked well or cannot be tolerated, or in patients who have demonstrated steroid dependence.	By subcutaneous injection (SC)

Drug Name (Brand)	Type*	Treatment	Administered
Vedolizumab (Entyvio®)	$\alpha_4 \beta_7$ Integrin Blocker	Treatment of moderate to severe Crohn's and colitis in adults. It is used when conventional medicines have not worked well enough or cannot be tolerated, and in patients who have not had satisfactory response with infliximab.	By intravenous (IV)
Ustekinumab (Stelara®)	Antibody to the p40 subunit of IL-12 and IL-23	Treatment for moderate to severe Crohn's disease in adults. It is used when conventional therapies have not worked or cannot be tolerated, or in patients who have failed or were intolerant to treatment with one or more TNF blockers.	First dose by intravenous. Subsequent doses by subcutaneous injection (SC)
Tofacitinib (XELJANZ®)	Tofacitinib citrate	Treatment for moderate to severe ulcerative colitis (UC) in adults. It is used when conventional medicines have not worked or cannot be tolerated, or in patients who were intolerant to TNF $\alpha$ inhibitors.	Oral tablets

**\*NOTE:** Description of types of biologics

- **Anti-TNF Biologics:** One of the signals involved in causing inflammation in patient with Crohn's and colitis is called tumour necrosis factor alpha (or TNF-alpha). Anti-TNF biologic medications help block those signals and instigate remission.
- **$\alpha_4 \beta_7$  Integrin Blockers Biologics or selective adhesion molecule inhibitors (SAM):** These biologics attempt to block the movement of some inflammatory cells to areas of inflammation in the gut.
- **Antibody to the p40 subunit of IL-12 and IL-23:** IL-12 and IL-23 are messenger chemicals involved in the inflammation of Crohn's and colitis. Anti-p40 medications block the signals of both IL-12 and IL-23, reduce inflammation, and instigate remission.

# BIOLOGIC TREATMENT GUIDELINES

When a biologic medication stabilizes your disease, the treatment guidelines recommend that you continue to adhere to your prescribed dosage and dosing schedules. Please speak to your prescribing physician before stopping any treatment or missing doses as it may result in the formation of anti-drug antibodies, which can result in infusion/injection reactions, and lose its effectiveness.

## SIDE EFFECTS OF BIOTHERAPIES

All medications you take have benefits and risks associated with them. Your doctor will work with you to determine your proper dosage to help you balance your symptoms and discuss the potential side effects.

## OTHER MEDICATIONS TO TREAT CROHN'S AND COLITIS

Beyond biologics, other types or classes of medications can also be prescribed to control inflammation. If you would like to know more about the other classes of medications, please check out our brochure - Prescription for Health available on our website at [crohnsandcolitis.ca/brochures](http://crohnsandcolitis.ca/brochures).

## EMERGING RESEARCH

Researchers are constantly finding better ways to treat Crohn's and colitis. Not only are they discovering new drug treatments, they are also finding improved ways to use the medications already employed in the fight against IBD.

# ABOUT CROHN'S AND COLITIS CANADA

**Crohn's and Colitis Canada** is the only national, volunteer-based charity focused on finding the cures for Crohn's disease and ulcerative colitis and improving the lives of children and adults affected by these diseases. We are one of the top two health charity funders of Crohn's and colitis research in the world and the largest non-governmental funder in Canada. We are transforming the lives of people affected by Crohn's and colitis (the two main forms of inflammatory bowel disease) through research, patient programs, advocacy, and awareness.

**Our Crohn's & Colitis – Make it stop. For life.** campaign will raise \$100 million by 2020 to advance our mission.

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For more information on Crohn's disease or ulcerative colitis visit our website **[crohnsandcolitis.ca](http://crohnsandcolitis.ca)** or call 1-800-387-1479

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