



# Biologics and biosimilars, what's the difference?

## What is a biologic?

A biologic is a type of drug treatment produced from living cells, created to target specific parts of the immune system and treat chronic diseases such as IBD. The most common biologics used to treat IBD are:

- **Remicade (infliximab)**
- **Humira (adalimumab)**
- **Stelara (ustekinumab)**
- **Entyvio (vedolizumab)**

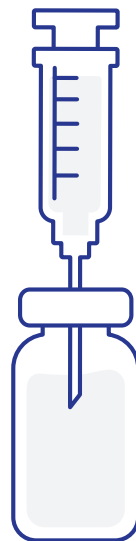


Biologics are not made of chemicals, but of proteins from large living cells. These cells are big, very delicate and complex. Researchers must genetically engineer a cell so that it produces a specific protein. The cells are grown in bioreactors and nourished with vital nutrients. After a few weeks, the proteins are harvested, impurities are removed and the biologic drug is processed and specially packaged. How a biologic is made is just as important as the proteins that go into it.

Biosimilars are also proteins made from living cells, but they are not made from the exact same cells used in the original biologic. When a biologic comes off patent, the company that made the original must share the drug's list of active ingredients, but it doesn't have to share how the drug is made - the manufacturing process is protected. Therefore, the process cannot be exactly duplicated, which results in the creation of a slightly different product. As the process cannot be precisely duplicated from beginning to end, it does not make it a generic product but a similar product.

## What is a biosimilar?

Once the patent on a biologic drug has expired, a version of the original biologic (innovator) can be made. This is called a biosimilar. Note that biosimilars are not the same as "generic" drugs, although the concepts are similar. A generic is an identical copy of a chemical drug. The exact chemical ingredients of a brand-name drug can be purchased and mixed together following a manufacturing process, much like following a recipe. The result is a product that is an exact replica - it is equally safe and effective as the brand-name product, but costs less.



A biosimilar will be similar in safety and efficacy to the original biologic, but the differences in how the drug is manufactured can result in structural differences and differences in impurities. These differences can lead to changes in how the drug moves through the body and how the body responds to the drug (immunogenicity).

Another difference between biologics and biosimilars is the price. Biosimilars are estimated to be priced up to 30 per cent less than an original biologic. Currently only one biosimilar, called Inflectra (a biosimilar of infliximab), is approved by Health Canada to be used in IBD. This approval applies only to adult IBD patients, not children, but should be an area of interest for transitioning IBD patients. IBD Source: [psoriasis.org/advance/-making-biologics](http://psoriasis.org/advance/-making-biologics)

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