



# Biologics, Biosimilars and Switching FAQ

## What are biologics?

- ▼ Biologics are medications used to treat a variety of autoimmune diseases, including some inflammatory forms of arthritis such as rheumatoid arthritis and psoriatic arthritis. They are complex biological compounds that are made by living cells—bacterial or yeast cells or cells obtained from plants or animals—rather than being manufactured chemically like most other drugs. Biologics work by calming the immune system to reduce pain, stiffness and other symptoms. Brand-name biologics are sometimes referred to as originator biologics.

## What are biosimilars?

- ▼ Biosimilars are biologics that are produced by manufacturers after the patent on an originator biologic expires. Because of the way biologics are produced, this isn't an exact copy, but it's very close. For this reason, different versions of the same biologic are called biosimilars, because they are very similar (but not identical) to the originator biologic and have similar safety and effectiveness.

## Are biosimilars the same as generic drugs?

- ▼ No. A generic drug is chemically manufactured to be an exact copy of the original drug, because the active ingredients are easy to duplicate (e.g. acetaminophen, a common pain reliever, is the same whether you buy a name brand or store brand). Due to the complexity and specialized processes involved to make them, biosimilars are only highly similar – not identical. The same would be true from one batch of originator biologics to the other – that batch would be highly similar to the starting batch. These differences do not impact the safety or efficacy of the drugs.

## Are biologics/biosimilars safe?

- ▼ Yes. Health Canada is responsible for making sure that all new drugs, including biologics/biosimilars, are safe, effective and of high quality. Health Canada evaluates all the information provided to confirm that the biosimilar and the originator biologic drug are similar and that there are no clinically meaningful differences in safety and efficacy between them.

## How do biologics/biosimilars work?

- ▼ In some people with arthritis, high levels of certain proteins are present in the blood and joints leading to inflammation, which can cause pain, swelling and stiffness. Originator biologics and biosimilars work to calm the body's overactive immune system by blocking these proteins and their ability to cause inflammation.

## Are biosimilars as effective as the originator biologic?

- ▼ Yes. Health Canada considers approved biosimilars to be the same 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."

## Will switching from my originator biologic to a biosimilar cause a health problem?

- ▼ You should not experience any negative effects from a switch. 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.