

Biologics & Biosimilars

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About Biologics

Biologics are a subset of a class of medications called disease-modifying antirheumatic drugs (DMARDs). DMARDs work to slow or stop the inflammatory process that can damage joints and internal organs. Biologics are powerful medicines that target proteins, cells and pathways responsible for triggering the symptoms and damage from inflammatory types of arthritis.

Four types of biologics tackle the inflammatory process in different ways:

- Tumor necrosis factor (TNF) inhibitors block TNF, a chemical that drives inflammation causing joint destruction.
- B-cell inhibitors hinder the autoimmune response by interfering with the production of abnormal antibodies.
- Selective co-stimulation modulators interfere with the activation of certain white blood cells called T cells, preventing immune system reactions that result in inflammation.
- Interleukin inhibitors target proteins involved in inflammation, including IL-1, IL-6, IL-12, IL-13 and IL-23.

In most cases, these drugs are prescribed when traditional DMARDs have not worked. However, a biologic may be prescribed first, depending on disease severity and other factors. Biologics have proven to be very effective, but they are expensive.

BEFORE YOU START...

- Tell your doctor if you have an active infection or have lived in areas where fungal infections are common.
- Be screened for tuberculosis and hepatitis B virus.
- Be up to date on your vaccines.
- Do not get a live vaccine while taking a biologic and biosimilar. Most other vaccines are OK, but talk to your doctor first.

About Biosimilars

Biosimilars mimic biologic medications, but they are often less expensive.

Unlike generic medications, which are exact copies of chemically designed medicines, biosimilars are not-quite-exact copies of biologics. Biologics are impossible to replicate perfectly because they are very large and complex molecules derived from living substances, such as human and animal cells, yeast and bacteria.

The U.S. Food and Drug Administration (FDA) has a different process for approving biosimilars than for

For More Information-

Arthritis Today Drug Guide arthritis.org/drug-guide Let's Get a Grip on Arthritis arthritis.org/letsgriparthritis

Arthritis Foundation Help Line 1-844-571-HELP (toll-free) other drugs. A manufacturer must show that a biosimilar drug is, among other things, as safe and effective as the original biologic – called the "reference product" – and works in the same way.

Taking Biologics and Biosimilars

Biologic and biosimilar drugs are administered by self-injection or intravenous infusion performed in a doctor's office. Most injection biologics use prefilled syringes that have an auto-injector and require refrigeration.

Side Effects of Biologics and Biosimilars

Adverse effects vary by medication, but the most common side effects of biologics and biosimilars include:

- Headache
- Injection site reactions (itching, redness, swelling), which can last up to five days
- Infusion-related reactions (difficulty breathing, rapid or weak pulse, nausea, vomiting), which may occur up to 24 hours after infusion

Contact your doctor immediately if you experience:

- Vision changes
- Shortness of breath,
- Red scaly patches
- cough or chest tightness
- Hives, rash, itching
- Nausea, vomiting, diarrhea

Risks of Biologics and Biosimilars

Biologics and biosimilars may increase the risk of serious infections and may cause "silent" infections (e.g., tuberculosis and hepatitis B) to reoccur. Some may increase the risk of certain types of cancer, cause new or worsening congestive heart failure or trigger multiple sclerosis.

Who Should Not Take Biologics or Biosimilars?

Many biologics and biosimilars are not recommended for women who are pregnant or nursing. Talk to your doctor if you are pregnant, nursing or planning to become pregnant.

If you are taking antibiotics for an infection, stop or don't start taking a biologic or biosimilar. The infection should be completely over before starting or resuming a biologic or biosimilar.



Are biologics and biosimilars interchange-

able? No. They are not exact replicas of biologics. Pharmacists will not automatically replace a brand name biologic with a biosimilar.

How much do these drugs cost? Biologics and biosimilars are more expensive compared to other medications, due to the high cost of manufacturing these complex drugs. Biologics can cost thousands of dollars per month. However, the drugs are often covered by insurance, and most drug makers offer discount programs to those in need. The discounts of biosimilars are not as great as you see with generic medications, but they appear to be at least 10 to 15 percent cheaper than biologics.

Can I stop taking my biologic or biosimilar if my disease goes into remission?

For some people, these medications work so well that all signs of their disease go away. If your arthritis has gone into remission, your rheumatologist can work with you to determine if you can stop or taper your biologic treatment. Remission does not equal a cure, so be sure to talk to your doctor immediately if you start to experience joint swelling or pain.

Should I choose a biosimilar over a

biologic? Always talk to your doctor about your treatment options. Together, you can weigh the risks and benefits of biosimilars and biologics as they apply to your disease activity.