

10 THINGS YOU SHOULD KNOW ABOUT BIOLOGICS & BIOSIMILARS

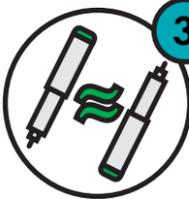


1 WHAT ARE BIOLOGICS?

Biologics are one type of disease-modifying anti-inflammatory drugs (DMARDs.) They help slow or stop the over-active inflammation that damages joints and organs in autoimmune diseases, like rheumatoid arthritis, juvenile arthritis, axial spondyloarthritis and psoriatic arthritis. There are two groups of biologics: "reference products" (or original biologics) and their biosimilars.

2 WHAT ARE BIOSIMILARS?

A biosimilar is a biologic that is highly similar to and has no clinically meaningful differences in purity, safety and effectiveness from the reference product, which was previously approved by the Food & Drug Administration (FDA).



3 WHAT ARE UNBRANDED BIOLOGICS?

Unbranded biologics are the same as name-brand, reference biologics, but without the labeling and branding. They may cost less, but it isn't clear whether and how they might be substituted for the name-brand drug. The FDA regards them as "equivalent."

4 WHY YOU NEED TO KNOW ABOUT BIOSIMILARS

The first biosimilar for arthritis came on the market in 2016. More will become available starting in 2023. Increased competition in the biologics market is expected to help drive down costs and make these drugs accessible to more patients, and manufacturers may offer financial assistance for biosimilars. You and your doctor might choose a biosimilar — or your insurer may require that you switch to one.



5 ARE BIOSIMILARS APPROVED BY THE FDA?

The FDA approves a biosimilar after rigorous testing and evaluation to ensure that it's as safe and effective as its reference product.

6 ARE BIOSIMILARS "GENERIC"?

No. Reference products and their biosimilars are made from living organisms, which are unique and complex. Generics are made from chemicals and can easily be copied. Biosimilars are not identical to the reference biologic because copying a living organism is impossible. But they have highly similar molecular structure, purity, safety and effectiveness.

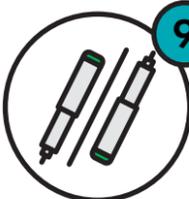


7 WHAT DO BIOLOGICS & BIOSIMILARS HAVE IN COMMON?

Reference biologics and their biosimilars are used for the same diseases and have the same potential side effects. They are prescribed at the same strength and dosage and both are given by self-injection (with a prefilled syringe and auto-injector) or by intravenous infusion in a medical facility.

8 DO YOU NEED A BIOLOGIC*?

Many patients never need biologic DMARDs because nonbiologic, conventional DMARDs (like methotrexate) control their disease well. If the conventional drug isn't effective enough, however, then their doctor may switch them to or add a biologic. People with severe and aggressive disease might start first on a biologic DMARD — either an reference product or a biosimilar.



9 COULD YOUR REFERENCE BIOLOGIC BE REPLACED?

A biosimilar becomes "interchangeable" with its reference product if it goes through additional testing that proves to the FDA that the products can be switched several times without raising the risk or lowering effectiveness. Your pharmacist may substitute a biosimilar for your reference biologic without permission only if it is FDA-approved as interchangeable. If it isn't, then your doctor must specifically prescribe the biosimilar.

Biosimilars are expected to cost less than their reference biologic, and your insurer may require that the lower-cost drug be given if one is available.

10 ARE THESE MEDICATIONS WORTH THE RISKS?

All drugs have risks. Because these drugs act on the immune system, they may raise the risks for other, potentially serious conditions. But it's important to know that your autoimmune disease makes you more vulnerable to some of these conditions, such as infection, lung or heart disease or cancer. Side effects vary by medication, but more common ones include headache, injection-site reactions (itching, redness, swelling) lasting up to five days, and infusion-related reactions (difficulty breathing, rapid or weak pulse, nausea, vomiting) up to 24 hours after infusion.



As always, talk to your doctor about your concerns about your medication. See our [Questions to Ask Your Doctor About Biologics & Biosimilars](#) for more information.

* Always tell your doctor before starting a biologic if you are pregnant, nursing or plan to become pregnant. Some biologics should not be taken under these circumstances.