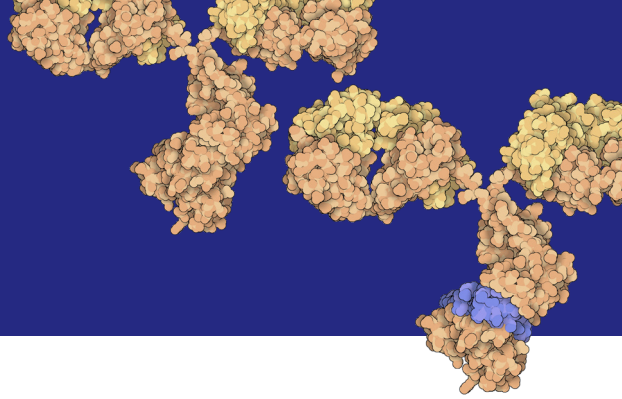
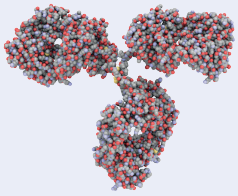
What Do I Need to Know About Biosimilars?



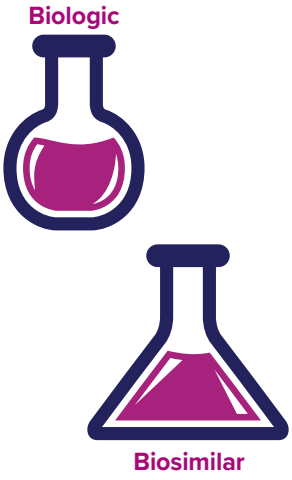
What Are Biologics?

Biologics are a special class of medicines that are approved by the United States (US) Food and Drug Administration (FDA) to diagnose, prevent, treat, or cure a disease. Many biologics are available for the treatment of serious conditions like cancer and autoimmune diseases. They are made from living organisms or cells and are usually large, complex molecules or combinations of molecules. Biologics cannot be taken by mouth; they must be injected. These features make them different from, and usually more expensive than, *small-molecule drugs*, which are made with simple chemical ingredients.

Small-Molecule Drug	Biologic
Small, simple structure (for example, aspirin: 21 atoms)	Medium to very large, complex structure (for example, monoclonal antibody: > 20,000 atoms)
	

What Are Biosimilars?

The FDA defines *biosimilars* as biologics that are "highly similar to and have no clinically meaningful differences from an existing FDA-approved *reference product*." This means that biosimilars have very similar safety, efficacy, and quality to a brand-name biologic that is already on the market. **Biosimilars work the same way in the body and are administered at the same dose and by the same route as the brand-name biologic.**



Biosimilars are developed after the patent expires on the brand-name biologic. They are meant to be less expensive versions of the reference product, but they are not *generic drugs*. Generic drugs are identical to an FDA-approved small-molecule drug and are relatively easy to make. In contrast, biosimilars are large and complex molecules, and it is not possible for another manufacturer to create an exact copy of the reference product. Minor differences in inactive parts of the molecule are allowed; these differences do not affect the biosimilar's safety or efficacy. In fact, different batches of the brand-name biologic also have minor differences and are not identical to each other, just like biosimilars.

How Are Biosimilars Approved?

Like all other prescription drugs, biosimilars must be approved by the FDA before they can be prescribed. As part of the approval process, the manufacturer conducts a variety of laboratory tests and clinical trials. Laboratory tests compare the biosimilar to the reference product to make sure that the biosimilar has the same structure and works the same way as the reference product. Clinical studies see how the drug affects people, and at least one clinical trial is conducted to directly compare the biosimilar to the reference product in patients with a disease that the reference product treats.

Only biosimilars that are shown to be safe, effective, and pure meet the FDA's high standards for approval. Like other biologics, biosimilars must be manufactured in FDA-licensed facilities, and they are subject to postmarketing surveillance, or *pharmacovigilance*, which is an ongoing process to monitor drug safety after FDA approval.

Safety and efficacy are the same as the reference product's

Same mechanism of action

Rigorous FDA testing and review

Biosimilars must be manufactured in FDA-licensed facilities that are committed to providing safe, effective products

When Is It Appropriate to Take a Biosimilar?

Several biosimilars are now available in the US, but none of them are currently considered an *interchangeable product*. That means that a pharmacist cannot automatically substitute a biosimilar when your healthcare provider prescribes a brand-name biologic.

The only way to receive a biosimilar is if your healthcare provider specifically prescribes it for you. Your healthcare provider may consider prescribing a biosimilar if you have never taken the reference product before or may consider switching your treatment from the reference product to a biosimilar because of the likelihood that you will get the same clinical benefit at a lower financial cost. Talk to your healthcare provider to see whether a biosimilar is right for you.

What Questions Should I Ask Before Taking a Biosimilar?

If your healthcare provider recommends treatment with a biosimilar, here are some questions you may want to ask:

- Why are you recommending this particular biosimilar instead of its reference product?
- Is this biosimilar covered by my health plan, and how much will I pay for it?
- What should I expect after starting or switching to this biosimilar?
- What are the side effects?
- Who do I call if I have additional questions or if I think I am having a side effect?

Term	Definition
Biologic	A medicine that is made through biotechnology and used to diagnose, prevent, treat, or cure a disease
Biosimilar	A medicine that is a highly similar version of an FDA-approved biologic
Generic Drug	A small-molecule drug that is identical to an original brand-name drug and can therefore be substituted for it
Interchangeable Product	A biosimilar that meets additional FDA requirements for approval and can be substituted for the biosimilar's reference product
Pharmacovigilance	A process (that occurs after a drug has been approved by the FDA) designed to detect, assess, understand, and prevent side effects and other drug-related problems
Reference Product	An FDA-approved biologic; a brand-name medication that has lost its patent protection
Small-Molecule Drug	A medicine that is made by combining chemical ingredients

Supported by an educational grant from Pfizer, Inc.

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