Biosimilars: Frequently Asked Questions

What is a biosimilar?

Like currently available biologic medications, biosimilars are medications that are made from natural and living sources like animal and plant cells and can be made of sugars, proteins, living cells, tissues, or a combination of these.[1]

A biosimilar:

- Is highly similar to an existing biologic drug (sometimes called the reference product).
- Comes in the same doses as the original biologic.
- Provides the same U.S. Food and Drug Administration (FDA) approved treatment benefits and has the same potential side effects as the original biologic.[1]

What are they used for?

They are used to treat and prevent conditions like rheumatoid arthritis, psoriasis, cancer, diabetes and many other conditions.

Are biosimilars safe?

Yes. They must go through a complete set of tests to show they are as safe and work as well as the original biologic (reference product). Then, the FDA approves them. Biosimilars are just as safe as the reference products. They work just as well, too.[2]

What is the difference between biosimilars and generics?

Generally, generics are made from chemicals. They are exact copies of brand-name medications. Biosimilars are made from natural materials, so they can only be highly similar to the original biologics (reference products).

Are biosimilars less expensive?

Usually yes, although pricing details may vary between products and depending on plan details.

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Compare brands, generics, biologics and biosimilars

	Brands (non-biologic)	Generics	Original biologics (Reference products)	Biosimilars
How is the medication developed?	Simple molecules usually produced with chemical ingredients	Simple molecules usually produced with chemical ingredients	Complex molecules produced in living cells using advanced science	Complex molecules produced in living cells using advanced science
Is it an exact copy?	Original product	Yes	Original (reference) product	It's not possible to make an exact copy, but they are tested to make sure they are as safe and effective as the original (reference) product.
Tested to be as safe and effective, having the same clinical results?	Yes	Yes	Yes	Yes, more extensive testing than generics due to how they're made.[1]
Approved by the FDA?	Yes	Yes	Yes	Yes
New prescription needed?	Not Applicable	No, the pharmacist will often automatically substitute	Not Applicable	Yes, unlike generics, pharmacist may need a new prescription

Learn more

Talk with your doctor to learn more about biosimilars and if they may be right for you. Or, visit these websites:

- **fda.gov/drugs/biosimilars/patient-materials**
- **cancer.org,** then enter **biosimilar** in the search box

1. Patient Materials | FDA **https://www.fda.gov/drugs/biosimilars/patient-materials** Accessed 09/03/2024
2. What Are Biosimilar Drugs? | Biosimilar Drugs for Cancer Treatment **https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/biosimilar-drugs/what-are-biosimilars.html** Accessed 09/03/2024

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