

What are biosimilars?

Biosimilars are drugs that are highly similar to other biologic drugs already approved by the U.S. Food & Drug Administration (FDA). To understand more about biosimilars, we will first talk about biologics.

What are biologics?

“Bio” in the word biologic means the study of living things. Biologics are drugs made from biological products, such as antibodies and proteins. They can come from all sorts of living things – animal and plant cells, and even bacteria. Biologics include things like vaccines and insulin. A common biologic used to treat HER2-positive breast cancer is trastuzumab (Herceptin®) which is made from antibodies.

How are biosimilars different from generic drugs?

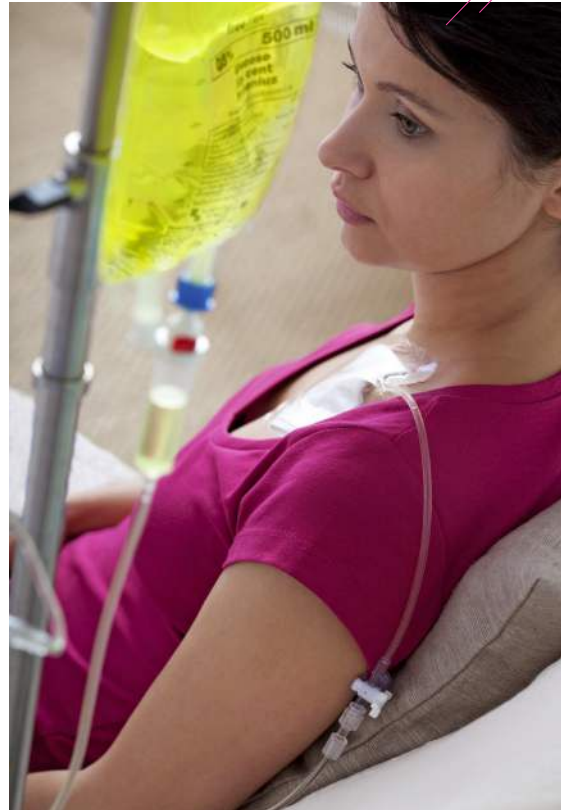
Biosimilars are “generic-like.” They are not the same as generic drugs because they contain biologics. For example, when a generic drug like ibuprofen is made, the active ingredients (chemicals) are an exact copy of the brand named drug. Many brand name drugs have generic versions.

Biosimilars are made in or from living things, so there’s not a way to make an exact copy of them. All biologics, including biosimilars, may vary slightly from one batch to the next. These small differences don’t affect how they work in the body.

How are biosimilars tested for safety and effectiveness?

Biosimilars can’t be used unless they’ve been approved by the FDA. Strict manufacturing guidelines are required to get FDA approval. Manufacturers must show biosimilars:

- are as safe as the original biologic
- are as effective as the original biologic
- have similar side effects as the original biologic
- are given the same way as the original biologic (for example, by injection or by vein (through an IV))



Resources

Susan G. Komen®

1-877 GO KOMEN
(1-877-465-6636)
komen.org

U.S. Food & Drug Administration (FDA)

1-888-INFO-FDA
(1-888-463-6332)
For more information on Biosimilars, click [here](#).

Related educational resources:

- [Biosimilars: What They Are and What You Need to Know](#)
- [HER2-Targeted Therapies for Early Breast Cancer](#)
- [Metastatic Breast Cancer: HER2-Targeted Therapies](#)
- [Questions to Ask Your Doctor: Biosimilars](#)
- [Treatment Overview for Early Breast Cancer](#)

Are biosimilars available today?

Many biosimilars have been approved in the U.S., and others are in development. The FDA-approved biosimilars for breast cancer treatment are all biosimilars to trastuzumab (Herceptin).

How much do biosimilars cost?

Due to the complex manufacturing process, biosimilars are costly to produce.

As more enter the market, competition may bring costs down over time. It's unknown how biosimilar costs will affect costs for patients.

Talk with your doctor

Your doctor can tell you whether a biosimilar may be part of your breast cancer treatment plan. Below are some questions you can ask your doctor about your treatment.

- Will I be getting a biosimilar as part of my treatment?
- Do biosimilars work the same way as the original biologic?
- How will the biosimilar be given?
- What side effects I should report to you?



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