

BIOSIMILARS



Questions for your doctor.

- What's your view on biosimilars?
- Am I getting a biosimilar?
- Why am I being given a biosimilar?
- Will this have any impact on my treatment/outcomes?
- What concerns should I report to you?

What is a biosimilar?

A biosimilar is a drug that is “highly similar” to another biologic drug already approved by the U.S. Food & Drug Administration (FDA). To understand more about a biosimilar, we will first discuss biologics.

What are biologics?

Biologics are a class of drugs used for a more targeted approach to cancer treatment. Due to advances in research, there has been a shift from things like surgery or chemotherapy for all, to a more targeted approach. Tumor characteristics, such as hormone receptors and HER2/overexpression, guide treatment today.

The prefix “bio” in the word biologic means biology or the study of living things. Biologics are powerful and complex drugs made from biological products like antibodies or proteins and can come from all sorts of living sources – animals, plants and even bacteria – not chemicals. Biologics include things like vaccines and insulin. A common biologic used to treat HER2-positive breast cancer is trastuzumab (Herceptin®).

How is a biosimilar different from a generic drug?

A biosimilar is not exactly the same as a generic drug but it is “generic-like”. When a company makes a generic drug like ibuprofen, for example, the active ingredients (chemicals) are an exact copy of the active ingredients in the branded version, Advil. Many branded drugs, such as allergy medicines or antibiotics, have generic versions.

However, a biosimilar is a biologic drug made in or from living things. Therefore, it's impossible to make an exact copy of that original drug. All biologics, including biosimilars, may vary slightly from one batch to the next. The small differences from batch to batch don't affect how they work in the body and manufacturers must meet strict guidelines to get FDA approval.



For more information, visit komen.org or call Susan G. Komen's breast care helpline at 1-877 GO KOMEN (1-877-465-6636) Monday through Friday, 9 AM to 10 PM ET.

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:

- Patients' Access to Treatments Webinar-Biosimilars <https://ww5.komen.org/Advocacy-Resources.aspx>
- Making Breast Cancer Treatment Decisions
- Targeted Therapies for HER2-Positive Breast Cancer
- Questions to Ask Your Doctor: Biosimilars

How are biosimilars tested for safety and effectiveness?

People in the U.S. who receive a biosimilar can be confident the product is as safe and effective as the original biologic. Biosimilars can't be used unless they are approved by the FDA.

To get FDA approval, the manufacturer must show the biosimilar is:

- safe;
- the same dose and strength as the original biologic;
- given the same way (injection or infusion (I.V.)) as the original biologic; and
- as effective as the original biologic.

Are biosimilars available today?

To date, more than 10 biosimilars have been approved in the U.S., and others are in development for various conditions. The first FDA-approved biosimilar in the U.S. was a drug to boost white blood cell counts. Biosimilars to trastuzumab (Herceptin®) are FDA-approved for breast cancer treatment and available in market.

What are the costs of biosimilars?

Due to the complex manufacturing process required, biosimilars are costly to produce. As more biosimilars enter the market, competition may bring costs down over time.

The list of resources is only a suggested resource and is not a complete listing of breast health and breast cancer materials or information. The information contained herein is not meant to be used for self-diagnosis or to replace the services of a medical professional. Komen does not endorse, recommend or make any warranties or representations regarding the accuracy, completeness, timeliness, quality or non-infringement of any of the materials, products or information provided by the organizations referenced herein.