

# Biosimilars:

## What Patients With Diabetes Need To Know

Biosimilars are types of biologic medications that are **safe** and **effective** for treating many chronic and severe conditions, including diabetes, as well as:



**Chronic skin diseases**  
(such as psoriasis)



**Macular Degeneration**



**Chronic bowel diseases**  
(such as colitis, Crohn's disease, and irritable bowel disorder)



**Arthritis**



**Diabetes**



**Kidney conditions**



**Multiple Sclerosis**



**Some cancers**  
(such as breast, lung, and colon)

The regulation of insulin as a biologic allows multiple companies to make biosimilar versions of “brand name” insulins, similar to how generics are versions of brand name drugs.

A biosimilar is very similar, but not identical, to an original biologic (also known as a reference product) that FDA has already approved. For biosimilars to be approved by FDA, studies must show that there are no differences in the safety and effectiveness of biosimilars and their original biologics.

Both a biosimilar and its original biologic:

- Are made from the same types of sources (e.g., living sources)
- Provide the same benefits when treating diseases or medical conditions
- Are given at the same strength and dosage
- Are not expected to cause new or worsening side effects

### What are biologic medications? How are they different from other types of medications?

Most biologics, including insulin, are made from living sources, such as animal cells and microorganisms like bacteria or yeast. Because biologics generally come from living sources and have natural differences, they can be more complicated to produce than drugs made from chemicals. Drugs made from chemicals, such as aspirin, can generally be more easily copied.

### Has insulin always been a biologic?

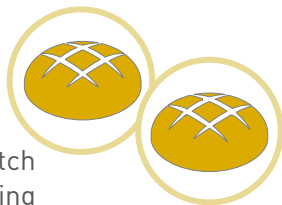
Although insulin is made in living cells, it was historically regulated as a drug made from chemicals. Insulin and other drugs that meet the criteria for a biologic are now regulated as biologics. This does not change the ingredients of insulin or how you obtain medication at the pharmacy.

For more information on biosimilars, visit  
[www.FDA.gov/biosimilars](http://www.FDA.gov/biosimilars)  
 and talk to your doctor to learn more.



FDA has approved many biosimilars and expects to approve more in the future. For more information about individual biosimilars, including insulin, and the conditions they treat, please visit <https://purplebooksearch.fda.gov>.

All biologic medications, including biosimilars, are similar to loaves of bread if they were made using the same recipe: No one loaf is an exact copy of another, but they are all the same type of bread. The same is true for biologics: Each batch is made with a mix of ingredients that include living sources. Because living sources have slight variations, each batch is not an exact copy, but each batch provides the same treatment benefits.



**Biosimilars may be available at a lower cost than the original biologics.** Similar to generic drugs, biosimilars may cost less because manufacturers rely on FDA's finding that the original biologics are safe and effective. The lower cost is not a reflection of the effectiveness or safety of biosimilars. Because of the lower cost, biosimilars may be covered by more insurance companies and offer patients additional treatment options.

**Biosimilars are safe and effective.** As it does with all medication approvals, FDA carefully reviews the data provided by pharmaceutical companies and takes a number of steps to ensure that all biosimilars, including insulin, meet standards for patient use. Patients and health care providers can rely on a biosimilar to be as safe and effective as the original biologic. FDA takes the same precautions to help ensure the safety and effectiveness of biosimilars as it does for all medications.

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## What are interchangeable biosimilars?

An interchangeable product is a biosimilar that may be substituted without consulting the prescribing doctor, because it meets additional requirements related to the potential for automatic substitution. This practice is called "pharmacy-level substitution" and is subject to state law.

Both biosimilars and interchangeable biosimilars are as safe and effective as the original product they were compared to.

## Why aren't biosimilars identical to the original biologics?

Because most biologics are made from living sources, it is normal for both biosimilars and original biologics to have minor differences between batches of the same medication. This means that biologics cannot be copied exactly, and that is why biosimilars are not identical to their original biologics.

FDA carefully reviews the differences between the original biologic and the biosimilar to ensure that biosimilars are as safe and effective as the original biologics.

For more information on biosimilars, visit

[www.FDA.gov/biosimilars](http://www.FDA.gov/biosimilars)

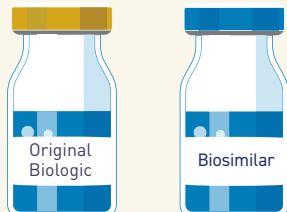
and talk to your doctor to learn more.



**Before approving a biosimilar, FDA:**



Carefully reviews data, studies, and tests to decide whether a biosimilar meets FDA's high standards for approval



Ensures that manufacturers show that there are no differences in side effects, including that the side effects of the biosimilar are not more frequent or more severe than those of the original biologic

**After approval, FDA:**



Continues to check on the quality of the biosimilar production



Reviews reports from patients and health care providers on the biosimilar's safety and effectiveness

**How will the availability of biosimilar insulins affect me or a person I care for?**

The most noticeable change is that patients can be prescribed a variety of additional insulin options once they are available, possibly at a lower cost, depending on your insurance coverage. Depending on the state law, a pharmacist may give you an interchangeable biosimilar insulin, much like they would substitute a generic for a brand-name drug. FDA does not control the cost of drugs, but you can learn more about the price of a specific biosimilar by contacting your pharmacy or insurance company.

As with all treatment decisions, you should talk to your health care providers and check other trusted sources of information related to your specific condition to learn more about biosimilar treatment options.

Biosimilars are a growing field of critical treatment options for a range of conditions. FDA is committed to educating patients and caregivers about biosimilars so they understand all potential treatment options. More detailed information on the approval process and published studies is available for doctors and patients on the FDA biosimilars website, [www.fda.gov/biosimilars](http://www.fda.gov/biosimilars).



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