

Looking at Biosimilar Medicines for IBD

There are a number of medicines that you can take for inflammatory bowel disease (IBD), including biologics and biosimilars.

What's a Biologic?

A biologic is a medicine produced by living cells like yeast, bacteria, or other cells. These cells are modified (changed) so that they make the active ingredient that is included in the medicine. Biologics can treat many types of diseases, including IBD.

What's a Biosimilar?

A biosimilar is a medicine that is created to be *similar* to the biologic. The biologic is called the reference medicine. A biosimilar is not exactly the same as the reference medicine (biologic) but it has the same effects in patients. It is also not a generic medicine because generics are identical to the original medicine (brand name).

The reason why biosimilars are not identical to the reference medicine is because biosimilars -- just like biologics -- are made from living cells, which are all unique. However, biosimilars must meet the same exact quality standards as biologics, so they are as safe and effective as biologics.

Do Biologics and Biosimilars Work the Same Way?

Yes. Even though biologics and biosimilars are not exactly the same, they can be used to treat the same conditions. They are both effective and safe.

Just like with biologics, you cannot take biosimilars if you have active tuberculosis (TB), other severe infections, or moderate to severe heart failure. Your doctor may check to see if you have TB or other infections before you start taking a biosimilar. You should also not get certain vaccines while taking a biosimilar. You should not take a biosimilar if you are pregnant or planning to become pregnant. Make sure you talk to your doctor about how to take vaccines safely, and about pregnancy.



There are several biosimilars that can treat moderate to severe IBD that are approved in Europe.

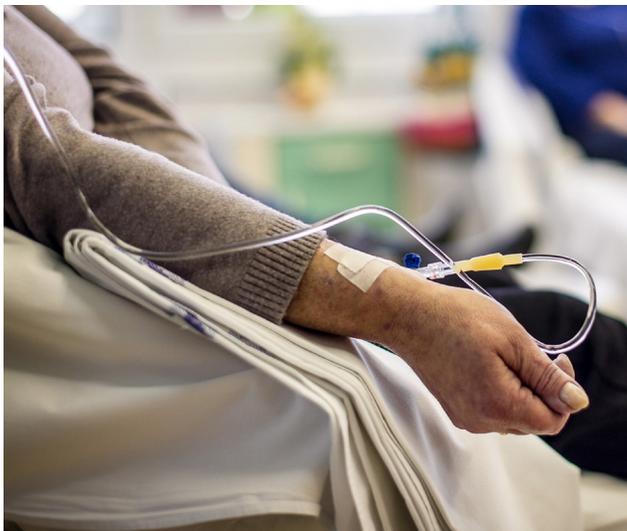
Biosimilars to the reference medicine adalimumab (Humira™)

These include Amgevita™, Hefiya™, Hulio™, Hyrimoz™, Idacio®, and Imraldi™. They are given via a shot (injection) every few weeks. Your doctor or nurse can show you (or a caregiver) how to give the shot at home.

Side effects include:

- Infections of nose and throat
- Injection-site reactions: redness, itching, bleeding, pain, or swelling
- Headaches
- Muscle and bone pain

Biosimilars to the reference medicine infliximab (Remicade™)



These include Inflectra™, Flixabi™, Remsima™, and Zessly™. These are given as an IV (intravenously) every few weeks. You will need to go to a medical facility, and it may take a few hours. There is a chance you may have a reaction to the medicine, so your doctor may give you other medicines before or during administration of the biosimilar IV. These additional medicines can help prevent any possible reactions you may have.

Side effects include:

- Viral infections: flu or cold sores
- Headache
- Colds
- Sinusitis (inflammation of the sinuses)
- Nausea
- Stomachache

Sometimes the side effects can be serious so it's important to call your doctor right away. Make sure you keep your follow-up visits. It's important to make sure your doctor knows how you are feeling.

What Happens If You Switch to a Biosimilar?

Biosimilars cost less than biologics so your doctor or hospital may switch you to a biosimilar if you are doing well and your IBD is being managed successfully on the reference medicine (biologic). Switching your medicine to a biosimilar shouldn't change how you are doing as biosimilars are as safe and effective as biologics.

Questions to Ask Your Doctor

- Do biosimilars and biologics work the same way?
- Is a biologic better than a biosimilar or biosimilar better than a biologic?
- Do biosimilars and biologics have the same side effects?
- Are biosimilars as safe as biologics?
- Do I need to go to a medical facility to get my medicine or can I take it at home?

