Biologics and biosimilars



What is a biologic?

A biologic is a medicine that is a protein.

- It is made in living cells.
- Other medicines such as ibuprofen or acetaminophen are chemicals. They are much smaller and easier to make than biologics.
- Biologics that are the first of their kind available to patients are called reference biologics.

Biologics are used to treat Crohn's disease, ulcerative colitis, juvenile rheumatoid arthritis and other diseases.

What is a biosimilar?

A biosimilar is a medicine that is "highly similar" to the reference biologic.

- Biosimilars are biologics.
- A reference biologic and its biosimilar will never be exactly the same, but they work the same way in the body.

What are some examples of biologics and biosimilars?

Reference biologics	Their biosimilars
Remicade (infliximab)	Inflectra (infliximab-dyyb) Renflexis (infliximab-abda Avsola (infliximab-axxq)
Rituxan (rituximab)	Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)
Avastin (bevacizumab)	Zirabev (bevacizumab-bvzr) Mvasi (bevacizumab-awwb)

Are biosimilars given the same way as biologics?

Yes – biosimilars are given the same way and at the same dose as their reference biologics. They are most often given as an injection (shot) or as an infusion through an I.V. or central venous access (CVAD) device.

What should I check when giving a biosimilar?

Biosimilars have similar names to their reference biologics. When giving a specific biosimilar, be sure to check the core part of the name, the 4 letter suffix and the brand name. See the example below:

suffix brand name core name Infliximab-dyyb (Inflectra®)

In case of an urgent concern or emergency, call 911 or go to the nearest emergency department right away.

Are biosimilars safe?

Yes - they are most often safe.

- Companies that make biosimilars have to prove they are as safe as reference biologics before they are allowed to sell them.
- Like other medicines, biosimilars may cause side effects. Biosimilars have the same side effects as their reference biologics. For example: Inflectra (infliximab-dyyb) has the same side effects as Remicade (infliximab).
- Talk with your child's doctor or pharmacist about the risks of taking a biosimilar.

Are biosimilars effective?

Yes - they are most often effective (work well).

- Companies that make biosimilars have to prove they are <u>as effective as their reference biologics</u> before they are allowed to sell them.
- Talk with your child's doctor or pharmacist about why your child needs to take a biosimilar and how they will take it.

Why use a biosimilar over a biologic?

Biosimilars are safe, effective and most often cost less than their reference biologics. Your insurance company may prefer to cover the cost (or part of the cost) of a biosimilar over its reference biologic. Talk with your insurance company if you have questions about what is covered.

Where can I learn more?

For more information, you may visit these websites:

- American Gastroenterological Association <u>gastro.org/practice-guidance/practice-updates/biosimilars/</u>
- U.S. Food & Drug Administration <u>www.fda.gov/drugs/biosimilars/patient-materials</u> (available in English and Spanish)
- American Pharmacists Association <u>www.pharmacist.com/biosimilar-basics-patients</u>

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This teaching sheet contains general information only. Talk with your child's doctor or a member of your child's healthcare team about specific care of your child.

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