

PHARMACY

Drug Information

Biologics and Biosimilars



What are Biologics?

- Biologics are biological medicines manufactured with ingredients from living cells or organisms. Compared to conventional medicines, biologics have larger molecules and are produced using complex technology.
- Biologics are used to treat a variety of diseases which include rheumatoid arthritis, psoriasis, inflammatory bowel disease and cancers.

What are Biosimilars?

- Biosimilars are biological medicines which are made available when the patent/licence for the reference biologic (originator/first biologic produced) expires. This makes the biological medicine more affordable and accessible for patients who are seeking treatment for their chronic conditions.
- Biosimilars contain the same active substances as their reference biologic. Biosimilars are highly similar to their reference biologic and are just as effective. For example, Remsima is the biosimilar for Remicade (reference biologic) and both of them contain the same active ingredient, infliximab.
- As biological medicines are made with ingredients from living cells or organisms, natural variability is expected. Therefore, no two batches of biological medicines will be exactly the same, and this applies for both the reference biologics and biosimilars. Minor differences may exist between biosimilars and their reference biologic, but these differences are not clinically significant. Overall, biosimilars have similar quality, safety and effectiveness as their respective reference biologic.

	Reference Biologic	Biosimilar
Quality of medicine	✓	✓
Safety for use	✓	✓
Efficacy	✓	✓
Relative cost to patient	\$\$\$	\$\$

Frequently Asked Questions

1. Are biosimilars safe?
 - Strict regulatory requirements are in place to ensure that all biological medicines are of good quality. Biosimilars are also assessed to have no clinically significant differences and are therapeutically equivalent to their reference biologic before being licensed for use.
2. If I am currently using a reference biologic, can I switch to its biosimilar?
 - While biosimilars are comparable to their reference biologic in terms of safety and effectiveness, their clinical effects may not be identical. Discuss with your doctor to assess if switching to a biosimilar is appropriate for your condition. Monitoring for any clinical response and adverse effects to the biosimilar is also required during the switch.
3. Are biosimilars affordable?
 - Biologics are generally costly when they are newly introduced, but biosimilars usually cost less than their reference biologic.
4. Are biosimilars the same as generic medicines?
 - No, they are not the same. Generic medicines are small chemical molecules which are deemed identical to the branded medicine in terms of absorption, effectiveness and safety. Biosimilars are large complex molecules which are highly similar to their reference biologics in terms of quality, safety and effectiveness. But due to the complex manufacturing process, minor and non-clinically significant differences may exist between biosimilars and its reference biologic.