

# Biosimilars for lymphoma

This information page is about biosimilars of biological medicines for lymphoma.

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## What is a biosimilar?

If your **treatment for lymphoma** includes a biological medicine, eg **rituximab**, you may be treated with the original brand of medicine or a different brand – a biosimilar. Developing medicines is very expensive, so a new medicine is patented by the company that developed it. Other companies cannot copy the medicine for a certain amount of time. Copies can only be made by other companies when the patent has run out.

Most medicines are made by chemical processes in a laboratory. When a medicine is an exact copy of the original, it is called a ‘generic’. There are generic versions of lots of chemical medicines, eg ibuprofen.

Biological medicines are more complex medicines made in a natural source (eg cells) and are more difficult to copy. Therefore even within the original brand of a biological medicine, there are differences between batches.

A biosimilar is a medicine that is developed to be highly similar to an existing biological medicine. Biosimilars may have very slight variations from the original, but they work in the same way as the original medicine. They are equally as effective.

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## How are biosimilars tested and approved?

A biosimilar goes through extensive tests in a laboratory and in small **clinical trials** to compare it with the original medicine. It has to match in quality, safety and efficacy (how well it works).

Then a large clinical trial is carried out in a group of people with a disease that the original is used for. This is to confirm that the safety and efficacy match the original.

A biosimilar does not have to be tested in every disease that the original is approved for. These tests were done with the original medicine so there is already evidence that the medicine works in those diseases. If the biosimilar works well in 1 of them, there is no reason it wouldn't behave in the same way in others.

The **European Medicines Agency** (EMA) looks at the evidence and decides whether to recommend that the biosimilar medicine is approved for use in Europe. It is then approved in the UK by the **Medicines and Healthcare products Regulatory Agency** (MHRA). At the time of writing, the UK's decision to leave the EU does not affect this approval process.

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## Why are biosimilars developed?

The availability of biosimilars increases competition, which should drive down costs. Copying a successful medicine is much quicker than developing a new medicine. Fewer clinical trials are needed if it is already known which diseases a medicine works in. As a result, biosimilars are usually much cheaper than the original medicine even though the quality of the medicines is the same.

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# Rituximab biosimilars for lymphoma

**Rituximab** is widely used to treat people with **non-Hodgkin lymphomas** that develop from a **B lymphocyte** (B cell). It is used alone or together with other medicines for lymphoma.

In 2017, the first rituximab biosimilar was approved for use in Europe. Now rituximab biosimilars can be used for the same people as original rituximab can.

Different brands of rituximab have different trade names. Which brand of rituximab your hospital uses depends on agreements with the pharmaceutical companies. As all the brands of rituximab are equally effective, this is likely to be decided by cost.

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## Frequently asked questions

Talk to your doctor if you have a question about biosimilars that isn't answered here or you are worried about switching to a biosimilar.

### What happens if this is my first treatment with rituximab?

If you have rituximab as part of your treatment, your hospital will give you the brand of rituximab they prescribe. Your medical team can give you more information about what to expect from your treatment.

### What happens if I am already having rituximab?

Your hospital might switch brands of rituximab as biosimilars become available. Rituximab biosimilars are only given intravenously (through a drip into a vein). If you are already having **intravenous rituximab**, your hospital

might want you to change brands if needed, eg if they don't have your current brand in stock. Your doctor or pharmacist can answer any questions you may have about switching brands.

Only one brand of **subcutaneous rituximab** (given by injection under the skin) is currently available. If you are having subcutaneous rituximab (by injection under the skin), you are likely to continue with this for your course of treatment.

## What should I do if I have any problems?

You are monitored in exactly the same way regardless of which brand of rituximab you have. All the brands of rituximab can cause similar **side effects**. If you experience problems with any treatment, report these promptly to your medical team.

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### References

These are some of the sources we used to prepare this information. The full list of sources is available on request. Please contact us by email at [publications@lymphoma-action.org.uk](mailto:publications@lymphoma-action.org.uk) or phone on **01296 619409** if you would like a copy.

- NHS England. What is a biosimilar medicine? Available at: [bit.ly/1QrdgZm](https://bit.ly/1QrdgZm) (Accessed April 2017)
- European Commission. What I need to know about biosimilar medicines. Information for patients. Available at: [bit.ly/2nNp66J](https://bit.ly/2nNp66J) (Accessed April 2017)

## Further reading

- [Antibody therapy for lymphoma](#)
- [Glossary](#)
- [Rituximab](#)
- [Targeted drugs for lymphoma](#)

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