

This information is about biosimilars of the drug trastuzumab (also known by the brand name Herceptin). To understand what a biosimilar is it may help to know more about how drugs are made.

How are breast cancer drugs made?

Most drugs are man-made by mixing chemical ingredients. If a company has created a unique drug they're likely to patent it. This means no other company can copy the chemical recipe of that drug.

Once a patent has expired (usually after around 10 years), other companies can reproduce the chemical recipe of a drug and sell copies called generics. To be approved for sale, generics must be exact copies of the original branded drug. In other words, they must have an identical chemical structure.

What are biologics?

Not all drugs are made from chemical recipes. Some, known as biological medicines or biologics, are made from living organisms such as bacteria or yeast, a bit like yoghurt is made using living cells. These include vaccines, human insulin and some cancer drugs like trastuzumab.

As with chemical drugs, once the patent for a biologic (the original drug) has expired, other companies can reproduce them. But compared to copying chemical recipes, this is a much more complicated, expensive and time consuming process. Trastuzumab (Herceptin) is an original biologic.

What are biosimilars?

Copies of biologics are called biosimilars, not generics, because they are not completely identical to the original drug. Batches of biologics are also not identical to each other because they contain active substances and come from living things.

Instead, biosimilars are manufactured to be highly similar versions of biologics already approved and in use.

Why am I being given a biosimilar rather than the original trastuzumab?

Biosimilars are usually provided at a much lower price than the original biologic. As both drugs are equally effective this helps the NHS to provide this important treatment at a reduced cost and the money saved can be used to improve other areas of treatment and care.

Hospitals have been instructed that if a cheaper biosimilar drug is available and it's equally effective, they should prescribe the biosimilar.

What happens if I'm already having the original trastuzumab?

The original trastuzumab (Herceptin) can be given as a drip into a vein (intravenously) or as an injection into the fatty tissue under the skin (subcutaneously). The subcutaneous form of the drug is mainly given to women with primary breast cancer after surgery. Trastuzumab biosimilars are currently only available intravenously.

If you're already having the original trastuzumab intravenously, you may be switched to a biosimilar. Your specialist breast cancer team will discuss this with you and can answer any questions you may have about switching.

If you're already having the original trastuzumab subcutaneously, you are likely to continue this rather than switch to an intravenous biosimilar. Your specialist breast cancer team can explain this in more detail.

Can I be confident that a trastuzumab biosimilar will be as effective as the original drug?

The companies that make biosimilars have to show licensing authorities very strict evidence of their effectiveness, safety and quality. Clinical studies have shown that the trastuzumab biosimilars work just as well and are as safe as the original biologic.

Biosimilars have been used by the NHS to treat other diseases, such as arthritis and some other cancers and experience shows that, when carefully approved, biosimilars are safe and effective.

Will I experience different side effects?

Results from clinical trials comparing trastuzumab biosimilars with the original biologic have shown there isn't a difference in the side effects. The side effects you experience while having a trastuzumab biosimilar should be the same as the side effects of the original biologic.

The European Medicines Agency has over ten years' experience of assessing biosimilar drugs and monitoring their safety. Over that time, it hasn't identified any relevant differences in the type, severity or frequency of side effects between biosimilars and the original biologics.

Further information

If you have any questions or concerns about having the trastuzumab biosimilar you can talk to a member of your specialist breast cancer team or your key worker.

The charities Breast Cancer Care and Breast Cancer Now have [printed](#) and online information about trastuzumab including who it is prescribed for, how long you'll have it and possible side effects.

Breast Cancer Care: www.breastcancercare.org.uk or call their Helpline on 0808 800 6000

Breast Cancer Now: www.breastcancernow.org



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