

Biosimilar Medicines

Frequently Asked Questions for Patients

Biological medicines

1) What is a biological medicine?

Biological medicines are made from living organisms, rather than being built as synthetic chemicals like other medicines, such as tablets. Because they are complex medicines made from living cells in a controlled way, there will be some natural and slight differences between them. Biological medicines were first used to treat people with serious illnesses in the UK over 20 years ago and they have improved the quality of life for millions of people worldwide.

2) What is a biosimilar medicine?

A biosimilar medicine is a biological medicine which is highly similar to the original ('originator' or 'reference') biological medicine already approved for use.

You may have heard of generic medicines, for example, a supermarket own-brand ibuprofen is the generic version of Nurofen®. Generic medicines are exact copies of the original medicine and are relatively simple to copy and manufacture.

The same idea applies to biosimilars, but it is not possible to make an exact copy of the original biological medicine due to the complex way in which they are made.

3) Are biosimilar medicines safe?

Biosimilar medicines are thoroughly tested and analysed both in the laboratory and in clinical trials. The authorities who regulate and licence medicines in the UK and Europe are confident that biosimilar medicines are as safe and effective as the original biological medicine.

To be licensed by the European Medicines Agency, a biosimilar medicine must have shown it has no clinically meaningful differences from the original biological medicine

and have met regulatory requirements in terms of quality, safety and efficacy compared to the original biological medicine.

Where the National Institute for Health and Care Excellence¹ (NICE) has recommended the original biological medicine in its guidance, they have stated that the same guidance will normally apply to a biosimilar version of that medicine.

4) Why does the NHS wish to use biosimilar medicines?

Biosimilar medicines represent very good value for the NHS as they are equally safe and effective, and are often much less costly than the original biological medicine. The NHS is asking clinical teams to use more biosimilar medicines so that the money saved can be reinvested in new medicines and treatments. This means that patients will be invited to switch to a biosimilar medicine. In 2017-18, the NHS saved over £200 million by using more biosimilar medicines, including in those patients with rheumatoid arthritis, psoriasis, ulcerative colitis and Crohn's disease.

5) How can I be confident that a biosimilar medicine will work as well as the original biological medicine for me?

Clinical studies have been conducted with groups of people to show that the biosimilar medicine works just as well and is just as safe as the original biological product. Patients switching to a biosimilar are expected to have the same response as if they had stayed on the original biological medicine.

Timescale

6) When will biosimilars of adalimumab be available?

Biosimilar versions of adalimumab will be available to NHS patients from December 2018 onwards. More biosimilar versions of adalimumab will become available over time. Your Trust will write to you again in December 2018 to provide further information about this.

Patient suitability

7) Who is best suited to switch to biosimilar adalimumab?

Biosimilar adalimumab is suitable for patients who are currently receiving Humira®, including those using Humira® for the following conditions:

- Rheumatoid arthritis

¹ <https://www.nice.org.uk/advice/ktt15/resources/biosimilar-medicines-58757954414533>

- Juvenile idiopathic arthritis
- Axial spondyloarthritis (including Ankylosing spondylitis)
- Psoriatic arthritis
- Psoriasis
- Paediatric plaque psoriasis
- Hidradenitis suppurativa
- Crohn's disease
- Paediatric Crohn's disease
- Ulcerative colitis
- Uveitis

Biosimilar adalimumab is suitable for patients who have only recently started to take Humira® and for those who have taken different biosimilar medicines in the past. If you have any questions about your suitability, please contact the biosimilar support team on 020 3447 2863 to discuss.

If you are currently receiving Humira® and it is not working well for you, you should discuss this with your clinical team at your next clinic appointment.

Process

8) How will I be informed if my hospital wants to use the new biosimilar medicines?

Your clinical team will contact you by letter. The letter will provide information about the new medicine and give details of who you can contact if you have questions.

9) Do I have to switch to the biosimilar or can I stay on Humira®?

The NHS currently spends in excess of £17.4 billion a year on medicines. The introduction of new and innovative medicines has contributed to the increase in cost of medicines used in hospital, growing from £4.2 billion in 2010/11 to £8.3 billion in 2016/17.

In order to sustain NHS finances and continue to improve health outcomes from medicines for all patients, it is important the NHS uses the most 'cost-effective' treatments available.

Biosimilar medicines are more cost-effective than the original biological product and they are equally safe and effective; therefore it would support the NHS if you were agreeable to the switch. If you have any questions, please contact the biosimilar support team on 0203 447 2863.

10) What is the process for patients to agree to a change to an adalimumab biosimilar?

If you are suitable for a biosimilar medicine, your clinical team will write to you in December to advise that your next prescription will be for biosimilar adalimumab. If you have any questions, please contact the biosimilar support team on 020 3447 2863.

11) What happens when my current prescription for Humira® runs out?

The clinical team at the hospital will be managing your prescription. If you are switching to a biosimilar your homecare or pharmacy team will ensure that you use all supplies of Humira® first, before you start to use the biosimilar medicine. They will also ensure that a supply of the biosimilar medicine is available before your existing supplies run out.

12) Would I need to go into hospital before I switch to a biosimilar of adalimumab?

There should be no need for you to go into your hospital department for a special visit.

13) What length of prescription will I have for the new medicine?

The length of prescription for the new medicine will not change.

14) Will I need training to administer the new medicine and if so, who will arrange the training for me?

It is important to note that there may be differences in the pen used to inject the medicine. Your homecare nursing support team will provide any training that is necessary.

15) What happens if I change to a biosimilar of adalimumab but I have side effects?

The biosimilar medicines are not expected to have any additional side effects. If you develop a side effect, which can happen with any medicine, please contact your clinical team at the hospital and let them know. You will then be able to talk to them about the best options for you.

All suspected side effects should be reported via the Yellow Card Scheme online: <https://yellowcard.mhra.gov.uk/>.

16) Can I switch back to Humira® if I don't feel as well on the biosimilar?

Your clinical team at the hospital will discuss any issues with you and agree the best way forward if you are experiencing any problems. It is important to be aware that the nature of your disease means that, each year, some people who have been stable on adalimumab will lose response to that medication and need a change of treatment. This is to be expected regardless of being on either Humira® or the biosimilar product.

17) Is there likely to be repeated switching between the different versions of adalimumab?

While repeated switching between biosimilar medicines is not currently recommended, in the future, if more versions of adalimumab become available, hospitals may work with patients to switch to a different medicine – but only if it is considered safe and effective.

Supply

18) Will I need to do anything different if I have a new homecare provider?

Your homecare provider will remain the same so there will be no changes to the way your medicines are delivered.

19) Will I need to do anything different if I receive my medicine from the hospital pharmacy?

Your hospital pharmacy will be able to provide the biosimilar medicine so there will be no changes to the way your medicines are provided.

Other

20) Will any savings from switching patients to biosimilar medicines be reinvested in the NHS?

All savings will be used to benefit patients. Switching to biosimilar medicines saved the NHS many millions of pounds already which have been reinvested in patient care. In the future, this will enable more patients to have access to these life-saving and life-enhancing treatments.

National information and support

The following patient organisations have contributed towards this patient information leaflet. Further information and support can be obtained from:



**CROHN'S &
COLITIS UK**

Website: <https://www.crohnsandcolitis.org.uk>
Email: info@crohnsandcolitis.org.uk
Telephone: 0300 222 5700

Further information on biosimilars: <https://www.crohnsandcolitis.org.uk/about-inflammatory-bowel-disease/publications/biologic-drugs-in-ibd>



NATIONAL ANKYLOSING SPONDYLITIS SOCIETY **NASS** UK

Website: <https://nass.co.uk/>
Email: admin@nass.co.uk
Telephone: 020 8741 1515

Further information on biosimilars: <https://nass.co.uk/managing-my-as/medication/biosimilars/>



nras
National Rheumatoid
Arthritis Society

Website: www.nras.org.uk
Email: helpline@nras.org.uk
Telephone: 0800 298 7650

Further information on biosimilars: <https://www.nras.org.uk/biosimilars>



Website: www.psoriasis-association.org.uk/
Email: mail@psoriasis-association.org.uk
Telephone: 01604 251 620

Further information on biologics: <https://www.psoriasis-association.org.uk/psoriasis-and-treatments/treatments/from-a-dermatologist>

Local information and support

The biosimilar support team are available to answer any questions you have about biosimilar medicines. Please contact 020 3447 2863 (9am to 5.30pm, Monday to Friday).