Biosimilars

Biologics

Psoriasis is a long term immune-mediated inflammatory disease (IMID) where the immune system becomes overactive and affects the skin. Currently, there is no cure for psoriasis however there are many well-established and targeted treatments that can make a real difference and help manage psoriasis effectively over time.

In the last three decades, biologic medicines have been launched and developed. Biologics are large complex medicines which are made using living cells. They target the underlying causes of inflammation in conditions such as psoriasis, psoriatic arthritis, rheumatoid arthritis, and inflammatory bowel disease. The introduction of these biologics has improved the management of psoriasis considerably. You can read more about biologics in our information sheet leaflet on Biologics for Psoriasis and Psoriatic Arthritis.

What are biosimilar medicines?

When the patent (copyright) of a biologic medicine expires, the original pharmaceutical company no longer has the sole right to make the medicine. This means that other companies can then produce their own version, which are known as biosimilars. Biosimilar medicines are treatments designed to closely match an existing biological medicine.

NHS England describes a biosimilar medicine as a biological medicine that is highly similar in quality, safety, and effectiveness to an existing, approved "reference" medicine. Manufacturers of biosimilar medicines must demonstrate that there are no clinically meaningful differences from the original and achieve the same results. They are approved for use after rigorous testing.

Psoriasis UK, Dick Coles House, 2 Queensbridge, Northampton, NN4 7BF
01604 251620 www.psoriasis-association.org.uk mail@psoriasis-association.org.uk
Registered Charity No. 1180666 and SC049563

Are biosimilars different from generic medicines?

Generic medicines are simple chemical copies of medicines. You will commonly come across examples of this when you purchase different brands of paracetamol or ibuprofen in a pharmacy.

Biologic medicines are large complex molecules and so, unlike generics, it is not possible to create an exact copy. Instead, biosimilar medicines are highly similar copies of biologic medicines. The small variations between biologic medicines and biosimilars do not impact how the medicine works.

Are biosimilars safe and effective?

Yes, biosimilars are safe and effective. They undergo rigorous testing to ensure they work in the same way and are just as safe as the original medicine.

What is Interchangeability?

Interchangeability means a biosimilar can be prescribed in place of the original medicine. The MHRA (Medicines and Healthcare products Regulatory Agency) in the UK, states that once authorised, a biosimilar is considered interchangeable with the original biologic medicine and other biosimilars associated with the same original biologic medicine.

Why might I be offered a biosimilar?

Biosimilars are equally effective and safe but are often more cost-effective, allowing wider and improved access to treatment.

How do I get biosimilars?

Biosimilars can only be prescribed by a Dermatology or Rheumatology Specialist who is responsible for your psoriasis / psoriatic arthritis care.

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If you are switching to a biosimilar

You will receive information in advance explaining why the switch is being made and providing reassurance that the biosimilar is expected to be just as safe and effective as your current medicine.

What information will your Healthcare Team provide?

Biosimilar medicines will have the same dose and frequency of injection as the original medicine. They may sometimes have a different device such as a pen or a syringe. Your clinical team will provide you with information outlined below:

- Explanation of the medicine brand switch
- When and how your biosimilar medicine will be provided
- Outline any changes to monitoring (there is generally no additional monitoring required)
- Contact information if you have any other questions
- Information regarding the injection device if there are any differences to be aware of or training and support needed.

BADBIR

Long-term data on safety and side effects is collected for all biologics prescribed for psoriasis. If you are prescribed a biologic or biosimilar, you should be asked to join the British Association of Dermatologists' Biologics and Immunomodulators Register (BADBIR) or the British Society for Rheumatology Psoriatic Arthritis Register (BSR-PsA). These are observational studies which include people with psoriasis or psoriatic arthritis who are using a biologic treatment.

The National Institute of Health and Care Excellence (NICE) recommends that all people with psoriasis receiving biologic therapy, who provide their consent, are entered onto the registries. Currently, over 160 hospitals in the UK and Ireland are taking part and recruiting people with psoriasis, BADBIR captures all systemic treatments marketed in the UK and has collected data since 2007 and accumulated over 100,000 person-years of follow-up. Data collected on the use of biosimilars is used to also demonstrate safety and efficacy outside of clinical trials.

A person with psoriasis is followed up throughout the study, for at least five years, via their Dermatologist. The person with psoriasis can choose to opt out of the study at any point. Those running the study carefully assess clinical data and the person's own recordings in a treatment

diary. Together, this data will help us to learn more about the safety, and effectiveness, of biologic therapies.

For more information on BADBIR, please see the website: www.badbir.org

For more information on BSR-PsA, please see the website: https://www.rheumatology.org.uk/improving-care/registers/psoriatic-arthritis

Biosimilars available for psoriasis and/or psoriatic arthritis:

Below is a list of the biosimilars that are currently available in the UK for psoriasis and/or psoriatic arthritis, listed by original biologic counterpart.

There may be information on the internet about other biosimilars that are currently available in other countries or still going through clinical trials. Unless they have been granted UK Marketing Authorisation, these will not be available in the UK.

The table below is correct at time of printing:

Biologic Name	Original Brand Name	Biosimilar Brand Names
Adalimumab	Humira®	Amgevita®, Hulio®, Idacio®, Imraldi®, Yuflyma®
Etanercept	Enbrel®	Benepali®, Erelzi®
Golimumab	Simponi®	Gobivaz®, Gotenfia®
Infliximab	Remicade®	Flixabi®, Inflectra®, Remsima®
Ustekinumab	Stelara®	Pyzchiva®, Steqeyma®, Uzpruvo®, Wezenla®

Biosimilars should be prescribed by brand name in line with MHRA guidance to prevent inadvertent switching. You should make a note of the name of biologic medicine you are prescribed.

Decisions about initiating treatment with a biosimilar, or switching should be shared, and both the healthcare professional prescribing the biosimilar and the patient should be aware of the brand name of the product received. This is important for traceability and reporting purposes.

Summary

Biosimilars are thoroughly tested to show that they are both safe and effective. Interchangeability is supported by MHRA, NHS England, and international agencies.

The information in this resource is not intended to replace that of a healthcare professional. If you have any concerns or questions about your treatment, do discuss this with your doctor and **always read the patient information leaflet** to make sure you are using your medicine correctly.

For more information, or for a list of resources used in producing this information sheet, please contact The Psoriasis Association.

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