

Birdshot Uveitis Society Factsheet

Biologics and biosimilars - what's the difference?

Please use this factsheet as background information to help discussion with your doctors. Individual cases may vary enormously and so the best information will always come from your doctors. The information in this sheet has been checked for accuracy by leading uveitis specialists.

Biologics and biosimilars – what's the difference?

A biologic is a medicine made from natural sources or living organisms. The first or original biologic on the market for any condition is called the originator product. Humira (adalimumab) and Remicade (infliximab) are examples of originator biologics used in treating Birdshot.

Because biologics are large, complex structures produced by complicated technological manufacturing methods, it is not possible for other manufacturers to make identical copies of originator biologic products.

A biosimilar is a biologic medicine that is, as its name suggests, highly similar to an already licensed biologic medicine in terms of quality, safety and effects. A biosimilar is specifically developed and licensed to treat the same disease(s) as the originator product. Biosimilars are licensed for use only after they have been extensively tested for quality, safety and effects and also compared against the originator product.

All biosimilars have their own brand names. Inflectra, Remsima and Renflexis are brand names of biosimilars already marketed as similar to Remicade (infliximab).

Why do I need to know about biosimilars?

Because several patents and 'periods of marketing exclusivity' for earlier biologic medicines are now expiring. Biosimilar versions of these medicines are becoming more widely available.

Is a biosimilar the same as a generic medicine?

No. Exact copies of biologics cannot be made, so a biosimilar should not be referred to as being a 'generic' medicine.

Will my biologic be switched to a biosimilar?

Not until you have first received information and an explanation from your doctor about a possible switch and you have been able to discuss this change with them.

In UK, the Medicines and Healthcare Products Regulatory Agency (MRHA) has recommended that all biologics should be prescribed by brand name to avoid any automatic substitution. At the point of dispensing, the pharmacist should confirm that you have received the biologic you expect.

Further information and support

Birdshot Uveitis Society (BUS) provides information and support to anyone with Birdshot. We are setting up a Birdshot patient database and biobank to help Birdshot scientists and researchers.

Membership of BUS is free of charge. It allows you access to Birdshot Days held in the UK, where professionals and patients come together to exchange information.

Useful Birdshot Uveitis Society links	
Email address:	mailto:info@birdshot.org.uk
Website:	https://birdshot.org.uk
Address:	Birdshot Uveitis Society, PO Box 64996,
	London SW20 8PT
Facebook support	https://facebook.com/groups/Birdshot/
group:	
Twitter:	https://twitter.com/birdshotcharity
YouTube channel:	https://www.youtube.com/user/Birdshot100/v
	<u>ideos</u>

The text of this leaflet has been written for birdshot patients by a birdshot patient and approved by clinician members of the National Birdshot Research Network

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