

2023 Adalimumab (Humira®) Biosimilars Information

Biosimilars are FDA-approved versions of original or "reference," biologics. They are highly similar to reference biologics with no clinically meaningful differences in purity, safety or effectiveness. Creating exact copies of reference biological products is not possible because they are made from living microorganisms, which are unique and complex.

The Biologics Price Competition and Innovation Act (BPCIA) of 2010 ensures that biosimilar medications must meet rigorous criteria before being FDA-approved. Biosimilars and reference products are both developed from living organisms, have similar molecular structures, and must meet the FDA's strict standards for quality and consistency. A reference product and its biosimilars are mostly offered at the same strengths and dosages and use the same modes of administration, i.e., by self-injection, or via infusion in a health care facility. Biosimilars are manufactured in FDA-licensed facilities.

On the next page is a list of biosimilars for adalimumab (*Humira*). All are approved to treat rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis, Crohn's Disease and ulcerative colitis. All except *Idacio* are also approved for hidradenitis suppurativa. *Amjevita*, *Cyltezo* and *Hadlima* are also approved for uveitis.

2023 Adalimumab (Humira®) Biosimilars



Drug Name	Company	Available	Inter- changeable ¹	Citrate-Free ² Formula Available	Latex-Free ³	Needle Size	Ease of Use Certified* Delivery Pen	Delivery Device Instructions	Patient Assistance Program Link
Abrilada ™	Pfizer	No	No	Yes	Yes	29G Syr. / 29G Pen	No		
Amjevita ™	Amgen	Yes	No	Yes	Yes	29G Syr. / 27G Pen	No	https://www.amjevita.com/sup portplus/how-to-take-amjevita	https://www.amjevita.com/supportplus/financial-support
Cyltezo ™	Boehringer Ingelheim	Yes	Yes	Yes	No	27G Syr. / 27G Pen	Yes	https://patient.boehringer- ingelheim.com/us/products/ cyltezo/starting-cyltezo/ injecting-cyltezo	https://patient.boehringer-ingelheim.com/us/products/ cyltezo/patient-support/swithching-to-cyltezo
Hadlima ™	Organon	Yes	No	Yes/No ⁴	Yes	29G Syr. / 29G Pen	Yes	https://www.hadlima.com	https://www.hadlima.com
Hulio ™	Viatris	No	No	Yes	Yes	29G Syr. / 29G Pen	No	https://www.hulio.com/how-to -use	https://www.hulio.com/support
Hyrimoz ™	Sandoz	Yes	No	No	No	29G Syr. / 29G Pen	No	https://www.hyrimoz.com	https://portal.trialcard.com/sandoz/hyrimoz/patient/ selection
Idacio ™	Fresenius Kabi	No	No	Yes	Yes	29G Syr. / 29G Pen	Yes	https://www.idacio.com/get-st arted-on-idacio	https://kabicare.us/patient/
Yuflyma ™	Celltrion	Yes	No	Yes	Yes	Unknown	No		
Yusimry ™	Coherus	Yes	No	Yes	Yes	Unknown	No	https://www.yusimry.com/ resources	https://www.yusimry.com

¹ If a biosimilar is FDA-approved as interchangeable and state law allows it, a pharmacy may replace a reference biologic with its biosimilar without the patient's or provider's approval.

More biosimilars are expected to be approved as interchangeable.

Last Updated: September, 2023

² Citrate-free injections are less painful than those with citrate.

³ Patients who are allergic to latex should use latex-free delivery devices.

⁴ Hadlima is available in citrate-free, high-concentration (40 mg/0.4 mL) and citrate-containing, low-concentration (40 mg/0.8 mL) formulations.

^{*} Products and packages certified by the Arthritis Foundation's Ease of Use program are tested and approved for people living with arthritis and chronic pain. Not all of these products have gone through the EOU testing process.