



# ¿Biológico o Biosimilar?

No importa cuál.  
He aquí la razón.

**Los biosimilares SON biológicos**  
Mismo medicamento, diferente marca

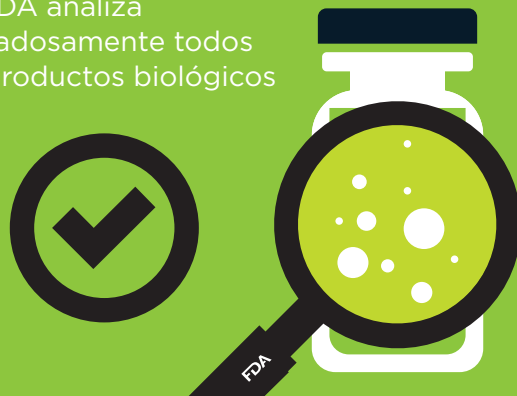


**Altos estándares de fabricación**  
Ambos se fabrican de la misma manera



**Rigurosos procesos de aprobación**

La FDA analiza cuidadosamente todos los productos biológicos



**Demostrado con el tiempo**

Usado durante más de 15 años para tratar más de 12 enfermedades<sup>1</sup>



**Resultados exitosos del tratamiento**

Docenas de estudios muestran que la eficacia y la inocuidad son las mismas<sup>2-27</sup>



**Acceso y apoyo al paciente**

Programas sólidos disponibles con todas las marcas



**En resumen: Comenzar y permanecer en terapia es clave, y los biosimilares no son un peligro. Puede sentirse seguro acerca de su tratamiento sin importar qué marca se seleccione.**

FDA = Administración de Alimentos y Medicamentos de los Estados Unidos.

#### Bibliografía:

1. Padda, I.S., Bhatt, R., Rehman, O. et al. Biosimilars use in medicine for inflammatory diseases. Updated 2022 Jan 6. In: StatPearls [internet]. Treasure Island, FL: StatPearls Publishing; 2022. [https://www.ncbi.nlm.nih.gov/books/NBK574572/#\\_NBK574572\\_pubdet\\_](https://www.ncbi.nlm.nih.gov/books/NBK574572/#_NBK574572_pubdet_)
2. Schellekens, H., Smolen, J.S., Dicato, M. et al. Safety and efficacy of biosimilars in oncology. *Lancet Oncol.* 2016;17:e502-e509.
3. Howden, C.W., Lichtenstein, G.R. Meeting report: AGA biosimilars roundtable. *Gastroenterology.* 2018;154:e1-e5.
4. Weise, M., Kurki, P., Wolff-Holz, E. et al. Biosimilars: The science of extrapolation. *Blood.* 2014;124:3191-3196.
5. Park, W., Hrycaj, P., Jeka, S. et al. A randomized, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: The PLANETAS study. *Ann Rheum Dis.* 2013;72:1605-1612.
6. Yoo, D.H., Hrycaj, P., Miranda, P. et al. A randomized, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: The PLANETRA study. *Ann Rheum Dis.* 2013;72:1613-1620.
7. Park, W., Yoo, D.H., Miranda, P. et al. Efficacy and safety of switching from reference infliximab to CT-P13 compared with maintenance of CT-P13 in ankylosing spondylitis: 102-week data from the PLANETAS extension study. *Ann Rheum Dis.* 2017;76:346-354.
8. Yoo, D.H., Prodanovic, N., Jaworski, J. et al. Efficacy and safety of CT-P13 (biosimilar infliximab) in patients with rheumatoid arthritis: Comparison between switching from reference infliximab to CT-P13 and continuing CT-P13 in the PLANETRA extension study. *Ann Rheum Dis.* 2017;76:355-363.
9. Fiorino, G., Caprioli, F., Daperno, M. et al. Use of biosimilars in inflammatory bowel disease: A position update of the Italian Group for the Study of Inflammatory Bowel Disease (IG-IBD). *Dig Liver Dis.* 2019;51:632-639.
10. Choe, J.Y., Prodanovic, N., Niebrzydowski, J. et al. A randomized, double-blind, phase III study comparing SB2, an infliximab biosimilar, to the infliximab reference product Remicade in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy. *Ann Rheum Dis.* 2017;76:58-64.
11. Danese, S., Bonovas, S., Peyrin-Biroulet, L. Biosimilars in IBD: From theory to practice. *Nat Rev Gastroenterol Hepatol.* 2017;14:22-31.
12. Kay, J., Chopra, A., Chandrashekar, S. et al. AB0420 Secondary efficacy outcomes from a phase 3 study support clinical equivalence between BOW015 and infliximab in patients with active rheumatoid arthritis on stable methotrexate doses. *Ann Rheum Dis.* 2015;74(Suppl 2):1034.
13. Taylor, P., Wyand, M., Knight, A. et al. FRI0163 Efficacy of the biosimilar BOW015, compared to originator infliximab, initiated at moderate and severe disease activity thresholds in rheumatoid arthritis. *Ann Rheum Dis.* 2016;75(Suppl 2):488-489.
14. Kay, J., Chopra, A., Lassen, C. et al. FRI0117 BOW015, a biosimilar infliximab: Disease activity and disability outcomes from a phase 3 active comparator study in patients with active rheumatoid arthritis on stable methotrexate doses. *Ann Rheum Dis.* 2015;73(Suppl 2):462-463.
15. Fiorino, G., Manetti, N., Armuzzi, A. et al. The PROSIT-BIO cohort: A prospective observational study of patients with inflammatory bowel disease treated with infliximab biosimilar. *Inflamm Bowel Dis.* 2017;23:233-243.
16. Smolen, J.S., Choe, J.Y., Prodanovic, N. et al. Safety, immunogenicity, and efficacy after switching from reference infliximab to biosimilar SB2 compared with continuing reference infliximab and SB2 in patients with rheumatoid arthritis: Results of a randomized, double-blind, phase III transition study. *Ann Rheum Dis.* 2018;77:234-240.
17. Tanaka, Y., Yamanaka, H., Takeuchi, T. et al. Safety and efficacy of CT-P13 in Japanese patients with rheumatoid arthritis in an extension phase or after switching from infliximab. *Mod Rheumatol.* 2017;27:237-245.
18. Jorgensen, K.K., Olsen, I.C., Goll, G.L. et al. Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): A 52-week, randomized, double-blind, non-inferiority trial. *Lancet.* 2017;389:2304-2316.
19. Meyer, A., Rudant, J., Drouin, J. et al. Effectiveness and safety of reference infliximab and biosimilar in Crohn disease: A French equivalence study. *Ann Intern Med.* 2019;170:99-107.
20. Ye, B.D., Pesegova, M., Alexeeva, O. et al. Efficacy and safety of biosimilar CT-P13 compared with originator infliximab in patients with active Crohn's disease: An international, randomized, double-blind, phase 3 non-inferiority study. *Lancet.* 2019;393:1699-1707.
21. Goll, G.L., Jørgensen, K.K., Sexton, J. et al. Long-term efficacy and safety of biosimilar infliximab (CT-P13) after switching from originator infliximab: Open-label extension of the NOR-SWITCH trial. *J Intern Med.* 2019;285:653-669.
22. Roder, H., Schnitzler, F., Borhardt, J. et al. Switch of infliximab originator to biosimilar CT-P13 in patients with Crohn's disease and ulcerative colitis in a large German IBD center. A one year, randomized and prospective trial (abstract). *United European Gastroenterol J.* 2018;8:A456.
23. Ilias, A., Szanto, K., Gonczi, L. et al. Outcomes of patients with inflammatory bowel diseases switched from maintenance therapy with a biosimilar to Remicade. *Clin Gastroenterol Hepatol.* 2019;17:2506-2513.e2.
24. Meyer, A., Rudant, J., Drouin, J. et al. The effectiveness and safety of infliximab compared with biosimilar CT-P13, in 3112 patients with ulcerative colitis. *Aliment Pharmacol Ther.* 2019;50:269-277.
25. Glintborg, B., Sørensen, I.J., Loft, A.G. et al. A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry. *Ann Rheum Dis.* 2017;76:1426-1431.
26. Strik, A.S., van de Vrie, W., Bloemsaat-Minekus, J.P.J. et al. Serum concentrations after switching from originator infliximab to the biosimilar CT-P13 in patients with quiescent inflammatory bowel disease (SECURE): An open-label, multicentre, phase 4 non-inferiority trial. *Lancet Gastroenterol Hepatol.* 2018;3:404-412.
27. Blauvelt, A., Lacour, J.P., Fowler, J.F. Jr. et al. Phase III randomized study of the proposed adalimumab biosimilar GP2017 in psoriasis: Impact of multiple switches. *Br J Dermatol.* 2018;179:623-631.

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