

Sandoz Biosimilar Portfolio

Immunology

Immune system disorders affect hundreds of millions of people worldwide and can severely impact quality of life and even life expectancy^{1,2,3}. These debilitating disorders include those affecting the joints (such as rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis), the skin (such as psoriasis) and the gut (such as Crohn's disease and ulcerative colitis).

Sandoz is the long-term partner supporting rheumatologists, dermatologists and gastroenterologists in advancing patient care without compromise. Our proven expertise and experience in biosimilars delivers high-quality affordable medicines in this therapy area.

We are committed to providing life-changing immunology therapies and have a robust biosimilar immunology portfolio with Erelzi^{®4}, Hyrimoz^{®5}, Zessly^{®6} and Rixathon^{®7}.

Sandoz biosimilar	Indication area
Hyrimoz [®] [adalimumab]	Immunology (rheumatology, gastroenterology, dermatology)
Zessly [®] [infliximab]	Immunology (rheumatology, gastroenterology, dermatology)
Erelzi [®] [etanercept]	Immunology (rheumatology, dermatology)

Endocrinology

Endocrinology diseases fall under a broad category of over or underproduction of hormones, altered tissue response to hormones or tumors arising from endocrine tissue¹. Some of these disorders can affect metabolism such as diabetes mellitus - with steadily increasing prevalence worldwide² - and impair fertility and growth.

Sandoz is committed to the Endocrinology community, supporting healthcare professionals and patient care givers. Sandoz is also focused on increasing physician and patient access to broader options for high-quality biologic medicines in Endocrinology.

We currently market Omnitrope[®] (recombinant human growth hormone, rhGH, Somatotropin), which was first approved in Australia in 2004³, then approved by the EMA in 2006.⁴

In addition, we are working on bringing multiple insulin biosimilars to the market in the next couple of years.⁵

Sandoz biosimilar	Indication area
Omnitrope [®] [somatotropin]	Endocrinology

Oncology

Cancer cases are predicted to almost double across the globe by 2024 to an estimated 668,535 per day. This will lead to a major rise in healthcare spending.¹ A deeper understanding of oncology is leading to increasing numbers of new cancer drugs, often at a high cost, resulting in spending that exceeds current budgets, threatening future resources for cancer care.

Biosimilars are key to creating a more sustainable future in cancer care and are estimated to save €8-10 billion annually in the EU.² Sandoz is proudly committed to helping shape this future.

We currently market Zarzio^{®3} / Zarxio^{®4}, Binocrit^{®5} and Ziextenzo^{®6}, used in supportive cancer care, and Rixathon^{®7}/Riximyo^{®8} to treat blood cancers. Sandoz also has a robust portfolio of proposed oncology biosimilars (trastuzumab and bevacizumab) we are bringing to market in the future.

Sandoz offers a comprehensive portfolio of oncology medicines with more than 50 medicines for the treatment of a wide range of cancers, including chemotherapeutics, biologics, hormones, and supportive care treatments.⁹

Sandoz biosimilar	Indication area
Binocrit [®] [epoetin alfa]	Oncology (supportive cancer care)
Zarzio [®] / Zarxio [®] [filgrastim]	Oncology (supportive cancer care)
Ziextenzo [®] [pegfilgrastim]	Oncology (supportive cancer care)
Rixathon [®] [rituximab]	Oncology (blood cancers), Immunology (rheumatology)

Immunology:

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- World Health Organization. Global report on psoriasis 2016. Available at: http://apps.who.int/iris/bitstream/10665/204417/1/9789241565189_eng.pdf [Accessed September 2022]
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7. European Medicines Agency. Rixathon® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/rixathon> [Accessed September 2022]

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2. World Health Organization. (2016). Global report on diabetes: executive summary. World Health Organization. <https://apps.who.int/iris/handle/10665/204874> [Accessed September 2022]
3. Australian Government. Department of Health, Therapeutic Goods Administration. Public Summary for Omnitrope® (Somatropin)
4. European Medicines Agency. Omnitrope® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/documents/product-information/omnitrope-epar-p...> [Accessed September 2022]
5. Sandoz International GmbH. Sandoz enters into commercialization and supply agreement for insulin biosimilars, anticipating growing demand as diabetes burden rises. Available from: <https://www.sandoz.com/news/media-releases/sandoz-enters-commercializati...> [Accessed September 2022]

Oncology:

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2. Dutta, B., Huys, I., Vulto, A.G. et al. (2020). Identifying Key Benefits in European Off-Patent Biologics and Biosimilar Markets: It is Not Only About Price! BioDrugs, 34, 159-170.
3. European Medicines Agency. Zarzio® /Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/zarzio> [Accessed September 2022]
4. Food and Drug Administration (FDA). Zarzio™ Package Insert. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125553s007lbl... . [Accessed: November 2022].
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6. European Medicines Agency. Zarzio® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/zarzio> [Accessed September 2022]
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8. European Medicines Agency. Riximyo® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/riximyo> [Accessed November 2022]
9. Sandoz (2019). Why opening the door to generics on day one is no brainer. Available at: <https://www.sandoz.com/news/why-opening-door-generics-day-one-no-brainer>. [Accessed September 2022.]

* No specific biosimilar pathway existed at the time in Australia, and so Omnitrope® was approved under the normal regulatory pathway in 2004. As biosimilar indication had not yet been established, the product was not established as a biosimilar at the time.

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