

Our biosimilars

Fresenius Kabi understands the importance of biosimilars and what they can bring to our patients' lives. This understanding is the driving force behind our knowledge, expertise and commitment to the science of biosimilars.



What is a biosimilar?

A biosimilar is a drug that is similar to another approved biopharmaceutical drug despite minor differences in clinically inactive components. It has no clinically meaningful differences in terms of effectiveness, safety or exposure from the reference product.¹

Fresenius Kabi is committed to putting essential medicines and technologies in the hands of people who help patients. Our heritage of providing high-quality and affordable treatments, while putting patients first, constitutes a fundamental part of our reputation, which we are carrying forward into our biosimilars offering in the areas of oncology and autoimmune disease.

Fresenius Kabi applies the same high-quality standards in developing and producing biosimilars as is required for the reference product. For biosimilar products to be approved, they should demonstrate high similarity to the reference product. This includes:

- **Comprehensive analytical studies** proving that the biosimilar product has physical, chemical and biological properties highly similar to the reference product
- **Clinical studies** demonstrating comparable efficacy, safety and immunogenicity profile to the reference product

1. European Medicines Agency (EMA). Biosimilars in the EU: Information guide for healthcare professionals. 2019. Available at: https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf (Accessed May 2022).

We are a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition



Biosimilars
by Fresenius Kabi
Living beyond disease

Our global footprint



- Sales and marketing organizations
- ▲ Production sites/compounding centers
- Research and development centers

As of May, 2022



Fresenius Kabi SwissBioSim GmbH
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It is the responsibility of each market unit to ensure that all materials produced for their market and prior to distribution are reviewed for compliance with the locally approved product labelling as well as applicable laws, regulations, codes and company policies through the applicable review process (medical, legal, regulatory - "MLR").

Fresenius Kabi biosimilars include compounds at different stages of development
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“Caring for life” is our philosophy

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. The company’s products and services are used to help care for critically and chronically ill patients.

Fresenius Kabi’s product portfolio comprises a comprehensive range of I.V. generic drugs, infusion therapies and clinical nutrition products as well as the devices for administering these products. In the field of biosimilars, Fresenius Kabi focuses on autoimmune diseases and oncology. Within transfusion medicine and cell therapies, Fresenius Kabi offers products for collection of blood components and extracorporeal therapies.

With its corporate philosophy of “caring for life”, the company is committed to putting essential medicines and technologies in the hands of people who help patients and finding the best answers to the challenges they face.

Our heritage highlights



1999:
Fresenius Kabi is formed following the acquisition of the international infusion business of Pharmacia & Upjohn (Kabi) by Fresenius



2005:
Expands **I.V. drug** portfolio and strengthens production network for devices



2007:
Enlarges its portfolio to cover **blood volume replacement, clinical nutrition and further I.V. drugs**



2008:
Expands into **oncology drugs**



2017:
Enters the growing biosimilars sector by acquiring a R&D pipeline with a focus on autoimmune diseases and oncology



2019:
Launch of **first autoimmune disease biosimilar** in Europe



2022:
Approval of **first oncology biosimilar** in Europe

Our global footprint

We serve customers worldwide, including hospitals, pharmaceutical wholesalers, pharmacies and ambulatory care organizations, as well as blood and plasma centers.

We believe that being close to our customers is a key driver of our success. Our global workforce spans 70 sales and marketing organizations and approximately 65 production and compounding centers and 25 R&D centers, where our employees are committed to improving the quality of life of patients each day.

Fresenius Kabi has a heritage of devotion towards providing high-quality and affordable products as well as a tradition of putting patients first, which we are now carrying forward into our biosimilar offering.

Our dedication and integrity underpin everything we do

Headquartered in Germany with a decentralized organization, we are well placed to meet the needs of our patients and customers worldwide. Each day, more than 41,000 employees share the passion of “caring for life”.

