

Table EU Approved / positive opinion biosimilars by molecule January 1. 2024

(not available in all EU-countries) (status CHMP-meeting December 15, 2023, 24 reference molecules, 87 biosimilar products, from which 2 pending EC approval)

Molecule	Reference	Biosimilar(s)
Adalimumab	Humira	Amgevita, Amsparity, Hefiya, Hukyndra, Hulio, Hyrimoz and Hyrimoz HCF, Idacio, Libmyris, Imraldi; Yuflyma (HCF formulation)
Aflibercept	Eylea	Yesafili
Bevacizumab	Avastin	Abevmy, Alymsys, Aybinto, Equidacent; MVasi, Onbevzi, Oyavas, Zirabev, Vegzelma
Eculizumab	Soliris	Bekemv, Epysqii
Enoxaparine	Clexane	Inhixa
Epoetin (α / Z)	Eprex	Absaemed, Binocrit, Epoetin alfa Hexal, Retacrit, Silapo
Etanercept	Enbrel	Benepali, Erelzi, Nepexto
Filgrastim	Neupogen	Accofil, Filgrastim Hexal, Grastofil, Nivestim, Ratiograstim, Tevagrastim, Zarzio
Follitropin alfa	Gonal-f	Bemfola, Ovaleap
Infliximab	Remicade	Flixabi, Inflectra, Remsima, Zessly
Insulin Aspart	Novo Rapid	Insulin Aspart Sanofi; Kixelle, Truvelog Mix30
Insulin glargine	Lantus	Abasaglar, Semglee
Insulin Human	Actrapid	Inpremia
Insulin Lispro	Humalog	Insulin Lispro Sanofi
Natalizumab	Tysabri	Tyruko
Pegfilgrastim	Neulasta	Cegfila, Fulphila, Grasustek, Nyvepria, Pelgraz, Pelmeg, Stimufend, Udenyca, Ziextenzo
Ranibizumab	Lucentis	Byooviz, Ranivisio, Ximluci, Rimmyrah (pending EUCie decision)
Rituximab	Mabthera IV	Blitzima, Ritemvia, Rixathon, Riximyo, Ruxience, Truxima
Somatropine	Genotropin	Omnitrope
Tocilizumab	RoActemra	Tyenne
Teriparatide	Forsteo	Movymia, Terrosa, Livogiga, Sondelbay, Kauliv
Tocilizumab	RoActemra	Tyenne
Trastuzumab	Herceptin IV	Herwenda, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera, Zercepac
Ustekinumab	Stelara	Uspruvo (pending EUCie decision)

Source: EMA website (<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/biosimilar-medicines-marketing-authorisation>) Accessed: January 5, 2024

20 Biosimilar-products in the licensing pipeline at EMA (Status: December 4, 2023).

Aflibercept (2x), Bevacizumab (1x for ocular injection), Denosumab (2x), Insulin aspart (1x), Insulin glargine (1x), Insulin human (1x), Omalizumab (1x); Rituximab (1x); Teriparatide (1x); Tocilizumab (1x); Trastuzumab (1x), Ustekinumab (6x)

FDA approved biosimilars (updates by Stanton Mehr)

see: <https://biosimilarsrr.com/us-biosimilar-filings/>