

APPROVED BIOSIMILAR PRODUCTS AROUND THE WORLD

Biosimilars Approved in Europe*

Product name	Active substance	Therapeutic area	Authorization date	Manufacturer/Company name
Abasaglar (previously Abasria)	insulin glargine	Diabetes	9 Sep 2014	Eli Lilly/Boehringer Ingelheim
Abseamed	epoetin alfa	Anaemia Cancer Chronic kidney failure	28 Aug 2007	Medice Arzneimittel Pütter
Accofil	Filgrastim	Neutropenia	18 Sep 2014	Accord Healthcare
Amgevita	Adalimumab	Crohn's disease Psoriasis Psoriatic arthritis Rheumatoid arthritis Spondylarthritis Suppurativa hidradenitis Ulcerative colitis Uveitis	22 Mar 2017	Amgen
Benepali	Etanercept	Axial spondyloarthritis Psoriatic arthritis Plaque psoriasis Rheumatoid arthritis	14 Jan 2016	Samsung Bioepis
Bemfola	follitropin alfa	Anovulation (IVF)	24 March 2014	Finox Biotech
Binocrit	epoetin alfa	Anaemia Chronic kidney failure	28 Aug 2007	Sandoz
Biograstim	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	15 Sep 2008 Withdrawn on 22 Dec 2016	CT Arzneimittel
Blitzima	Rituximab	Non-Hodgkin lymphoma Chronic B-cell lymphocytic leukaemia	CHMP positive opinion on 18 May 2017	Celltrion
Epoetin alfa Hexal	epoetin alfa	Anaemia Cancer Chronic kidney failure	28 Aug 2007	Hexal
Erelzi	Etanercept	Ankylosing spondylitis Juvenile rheumatoid arthritis Psoriasis Psoriatic arthritis Rheumatoid arthritis	27 Jun 2017	Sandoz
Filgrastim Hexal	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	6 Feb 2009	Hexal
Filgrastim ratiopharm	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	15 Sep 2008 Withdrawn on 20 Apr 2011	Ratiopharm

Flixabi	Infliximab	Ankylosing spondylitis Crohn's disease Psoriatic arthritis Psoriasis Rheumatoid arthritis Ulcerative colitis	26 May 2016	Samsung Bioepis
Grastofil	Filgrastim	Neutropenia	18 Oct 2013	Apotex
Imraldi	Adalimumab	Ankylosing spondylitis Arthritis Crohn's Disease Hidradenitis suppurativa Psoriatic arthritis, Psoriasis Rheumatoid arthritis Ulcerative colitis Uveitis	CHMP positive opinion 23 Jun 2017	Samsung Bioepis
Inflectra	Infliximab	Ankylosing spondylitis Crohn's disease Psoriatic arthritis Psoriasis Rheumatoid arthritis Ulcerative colitis	10 Sep 2013	Hospira
Inhixa	enoxaparin sodium	Venous thromboembolism	15 Sep 2016	Techdow Europe
Insulin lispro Sanofi	Insulin lispro	Diabetes mellitus	CHMP positive opinion on 18 May 2017	Sanofi-Aventis
Lusduna	insulin glargine	Diabetes	4 Jan 2017	Merck (MSD)
Movymia	Teriparatide	Osteoporosis	11 Jan 2017	Stada Arzneimittel
Nivestim	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	8 Jun 2010	Hospira
Omnitrope	Somatropin	Pituitary dwarfism Prader-Willi syndrome Turner syndrome	12 Apr 2006	Sandoz
Ovaleap	follitropin alfa	Anovulation (IVF)	27 Sep 2013	Teva Pharma
Ratiograstim	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	15 Sep 2008	Ratiopharm
Remsima	Infliximab	Ankylosing spondylitis Crohn's disease Psoriatic arthritis Psoriasis Rheumatoid arthritis Ulcerative colitis	10 Sep 2013	Celltrion
Retacrit	epoetin zeta	Anaemia Autologous blood transfusion Cancer Chronic kidney failure	18 Dec 2007	Hospira
Ritemvia	Rituximab	Wegener granulomatosis Microscopic polyangiitis Non-Hodgkin Lymphoma	CHMP positive opinion on 18	Celltrion

			May 2017	
Rixathon	Rituximab	Chronic B-cell lymphocytic leukaemia Microscopic polyangiitis Non-Hodgkin Lymphoma Rheumatoid arthritis Wegener granulomatosis	19 Jun 2017	Sandoz
Riximyo	Rituximab	Chronic B-cell lymphocytic leukaemia Microscopic polyangiitis Non-Hodgkin Lymphoma Rheumatoid arthritis Wegener granulomatosis	CHMP positive opinion on 21 April 2017	Sandoz
Silapo	epoetin zeta	Anaemia Autologous blood transfusion Cancer Chronic kidney failure	18 Dec 2007	Stada Arzneimittel
Solymbic	Adalimumab	Ankylosing spondylitis Crohn's disease Psoriasis Psoriatic arthritis Rheumatoid arthritis Hidradenitis suppurativa Ulcerative colitis	22 Mar 2017	Amgen
Terrosa	Teriparatide	Osteoporosis	4 Jan 2017	Gedeon Richter
Tevagrastim	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	15 Sep 2008	Teva Generics
Thorinane	enoxaparin sodium	Venous thromboembolism	15 Sep 2016	Pharmathen
Truxima	Rituximab	Chronic lymphocytic leukaemia Granulomatosis with polyangiitis Microscopic polyangiitis Non-Hodgkin's lymphoma Rheumatoid arthritis	17 Feb 2017	Celltrion
Tuxella	Rituximab	Wegener granulomatosis Microscopic polyangiitis Non-Hodgkin Lymphoma Chronic B-cell lymphocytic leukaemia	CHMP positive opinion on 18 May 2017	Celltrion
Valtropin	Somatropin	Pituitary dwarfism Turner syndrome	24 Apr 2006 Withdrawn on 10 May 2012	BioPartners
Zarzio	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	6 Feb 2009	Sandoz

*<http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe>

Biosimilars Approved in the United States*

Amjevita (adalimumab- atto)	adalimumab	Ankylosing spondylitis Crohn's disease Juvenile arthritis Psoriatic arthritis Psoriasis Rheumatoid arthritis Ulcerative colitis	23 Sep 2016	Amgen
Basaglar [#]	insulin glargine	Diabetes	16 Dec 2015	Eli Lilly/Boehringer Ingelheim
Epoetin Hospira	epoetin alfa	Anaemia (chronic kidney disease, Zidovudine, chemotherapy) Reduction of allogeneic red blood cell transfusions	Recommended for approval by FDA's Oncologic Drugs Advisory Committee (ODAC) on 25 May 2017	Pfizer (Hospira)
Erelzi (etanercept-szsz)	etanercept	Axial spondyloarthritis Polyarticular juvenile idiopathic arthritis Psoriatic arthritis Plaque psoriasis Rheumatoid arthritis	30 Aug 2016	Sandoz
Inflectra (infliximab- dyyb)	infliximab	Ankylosing spondylitis Crohn's disease Psoriatic arthritis Psoriasis Rheumatoid arthritis Ulcerative colitis	5 Apr 2016	Pfizer (Hospira)
Renflexis (infliximab-abda)	infliximab	Ankylosing spondylitis Crohn's disease Psoriatic arthritis Psoriasis Rheumatoid arthritis Ulcerative colitis	21 Apr 2017	Samsung Bioepis
Zarxio (filgrastim-sndz)	filgrastim	Autologous peripheral blood progenitor cell collection and therapy Bone marrow transplantation Cancer Myeloid leukaemia Neutropenia	6 Mar 2015	Sandoz

*<http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-the-US>

Biosimilars Approved in Japan*

Product name [JAN]	Active substance	Therapeutic area**	Authorization date	Manufacturer/Company name
Epoetin alfa BS [epoetin alfa biosimilar 1]	epoetin alfa	Anaemia Renal anaemia	20 Jan 2010	JCR Pharmaceuticals
Filgrastim BS [filgrastim biosimilar 1]	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	21 Nov 2012	Fuji Pharma/Mochida Pharmaceutical
Filgrastim BS [filgrastim biosimilar 3]	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	24 Mar 2014	Sandoz
Filgrastim BS [filgrastim biosimilar 2]	Filgrastim	Cancer Haematopoietic stem cell transplantation Neutropenia	28 Feb 2013	Teva Pharma Japan/Nippon Kayaku
Infliximab BS (Remsima) [infliximab biosimilar 1]	Infliximab	Crohn's disease Rheumatoid arthritis Ulcerative colitis	4 Jul 2014	Celltrion/Nippon Kayaku
Insulin glargine BS [insulin glargine biosimilar 1]	insulin glargine	Diabetes	26 Dec 2014	Eli Lilly/Boehringer Ingelheim [2]
Insulin glargine BS [insulin glargine biosimilar 2]	insulin glargine	Diabetes	28 Mar 2016	Biocon/Fujifilm Pharma [3]
Nesp	darbepoetin alfa	Anemia Cancer Chronic kidney failure	13 Sep 2013	Kyowa Hakko Kirin
Somatropin BS	somatropin	Growth hormone deficiency Turner syndrome	22 Jun 2009	Sandoz

*<http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Japan>

Biosimilars Approved in Latin America*

Product name	Active substance	Therapeutic area	Countries marketed	Company	Latin American partner
Etanar	etanercept	Ankylosing spondylitis Arthritis Psoriasis	Colombia	Shanghai CP Goujian	LaFrancol
Fiprima	filgrastim	Neutropenia	Brazil	Eurofarma Laboratórios	Not applicable
Kikuzubam	rituximab	Rheumatoid arthritis Non-Hodgkin lymphoma Leukaemia	Mexico	Probiomed	Not applicable
Novex	rituximab	Rheumatoid arthritis Non-Hodgkin lymphoma Leukaemia	Argentina	mAbxience	Laboratorio Elea
Reditux/ Tidecron	rituximab	Rheumatoid arthritis Non-Hodgkin lymphoma Leukaemia	Bolivia, Chile, Ecuador, Paraguay, Peru	Dr Reddy's Laboratories	CF Recalcine (Chile) Western Pharmaceutical (Ecuador) Farmindustria (Peru) FAPASA (Paraguay)
Remsima	infliximab	Ankylosing spondylitis Crohn's disease Psoriasis Psoriatic arthritis Rheumatoid arthritis Ulcerative colitis	Brazil, Colombia Venezuela	Celltrion/ Hospira	Amarey Nova Medical

*<http://www.gabionline.net/Biosimilars/General/Similar-biotherapeutic-products-approved-and-marketed-in-Latin-America>