

## Biosimilar medicines authorised via the EMA

Last updated 12/11/2019 (LB)



[www.biosimilars-nederland.nl](http://www.biosimilars-nederland.nl)

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Pegfilgrastim Mundipharma	oct/19	Neutropenia	Mundipharma Biologics S.L.	Pending EC decision
Pegfilgrastim (Grasustek®)	apr-19	Neutropenia	Juta Pharma GmbH	apr-19
Adalimumab (Idacio®)	jan-19	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric	Fresenius Kabi	apr-19
Adalimumab (Kromea®)	jan-19	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric	Fresenius Kabi	apr-19
Bevacizumab (Zirabev®)	dec-18	Colorectal Neoplasms Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Uterine Cervical Neoplasms	Pfizer	feb-19
Trastuzumab (Ogivri®)	okt-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Mylan	dec-18
Pegfilgrastim (Fulphila®)	sep-18	Neutropenia	Mylan	nov-18
Pegfilgrastim (Pelmeg®)	sep-18	Neutropenia	Cinfa Biotech S.L.	nov-18
Pegfilgrastim (Ziextenzo®)	sep-18	Neutropenia	Sandoz	nov-18
Pegfilgrastim (Pelgraz®)	jul-18	Neutropenia	Accord Healthcare	sep-18
Pegfilgrastim (Udenyca®)	jul-18	Neutropenia	ERA Consulting	sep-18
Adalimumab (Hulio®)	jul-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric	Mylan	sep-18
Adalimumab (Halimatoz®)	mei-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	jul-18

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Adalimumab (Hyrmoz®)	mei-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric	Sandoz	jul-18
Adalimumab (Hefiya®)	mei-18	Juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	jul-18
Trastuzumab (Trazimera®)	mei-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Pfizer	jul-18
Trastuzumab (Kanjinti®)	mrt-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Amgen	mei-18
Infliximab (Zessly®)	mrt-18	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Sandoz	mei-18
Insulin glargine (Semglee®)	jan-18	Diabetes Mellitus	Mylan	mrt-18
Trastuzumab (Herzuma®)	dec-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Celltrion	feb-18
Bevacizumab (Mvasi®)	nov-17	Fallopian tube neoplasms, Non-Small-Cell Lung Carcinoma, ovarian neoplasms, Renal Cell Carcinoma, Peritoneal Neoplasms, Breast Neoplasms	Amgen	jan-18
Trastuzumab (Ontruzant®)	sep-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Samsung Bioepis	nov-17
Adalimumab (Imraldi®)	jun-17	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and uveitis	Samsung Bioepis	aug-17
Insulin Lispro (Insulin lispro Sanofi®)	may-17	Diabetes mellitus	Sanofi	jul-17
Rituximab (Blitzima®)	may-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	jul-17
Rituximab (Ritemvia®)	may-17	Non-Hodgkin's lymphoma, granulomatosis with polyangiitis and microscopic polyangiitis	Celltrion	jul-17

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Etanercept (Erelzi®)	apr-17	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, paediatric plaque psoriasis.	Sandoz	jun-17
Rituximab (Riximyo®)	apr-17	Non-Hodgkin's lymphoma, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	jun-17
Rituximab (Rixathon®)	apr-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	jun-17
Adalimumab (Amgevita®)	jan-17	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and uveitis	Amgen	mrt-17
Rituximab (Truxima®)	dec-16	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Celltrion	feb-17
Teriparatide (Movymia®)	nov-16	Osteoporosis	STADA Arzneimittel	jan-17
Teriparatide (Terrosa®)	nov-16	Osteoporosis	Gedeon Richter	jan-17
Enoxaparin (Inhixa®)	jul-16	Prophylaxis of venous thromboembolic disease, deep vein thrombosis, pulmonary embolism, acute coronary syndrome and extra corporeal haemodialysis	Techdow	sep-16
Enoxaparin (Thorinane®)	jul-16	Prophylaxis of venous thromboembolic disease, deep vein thrombosis, pulmonary embolism, acute coronary syndrome and extra corporeal haemodialysis	Pharmathen	sep-16
Infliximab (Flixabi®)	mrt-16	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Samsung Bioepis	mei-16
Etanercept (Benepali®)	nov-15	Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis	Samsung Bioepis	jan-16
Filgrastim (Accofil®)	jul-14	Neutropenia	Accord Healthcare	sep-14
Insulin glargine (Abasaglar®)	jun-14	Diabetes Mellitus	Eli Lilly	sep-14
Follitropin alfa (Bemfola®)	jan-14	Anovulation	Finox	mrt-14
Filgrastim (Grastofil®)	jul-13	Neutropenia	Apotex	okt-13

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Infliximab (Remsima®)	jun-13	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Celltrion	sep-13
Infliximab (Inflectra®)	jun-13	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Hospira	sep-13
Follitropin alfa (Ovalean®)	aug-13	Anovulation	Teva	sep-13
Filgrastim (Nivestim®)	mrt-10	Neutropenia, Hematopoietic Stem Cell Transplantation. Cancer	Hospira/Pfizer	jun-10
Filgrastim (Filgrastim Hexal®)	nov-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hexal	feb-09
Filgrastim (Zarzio®)	nov-08	Neutropenia, Hematopoietic Stem Cell Transplantation. Cancer	Sandoz	feb-09
Filgrastim (Ratiograstim®)	jul-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Ratiopharm	sep-08
Filgrastim (Tevaagrastim®)	jul-08	Neutropenia, Hematopoietic Stem Cell Transplantation. Cancer	Teva	sep-08
Epoetin zeta (Retacrit®)	oct-07	Anaemia, kidney Failure, chronic blood transfusion. autologous cancer	Hospira	dec-07
Epoetin zeta (Silapo®)	oct-07	Anaemia, kidney Failure, chronic blood transfusion. autologous cancer	Stada	dec-07
Epoetin alfa (Abseamed®)	okt-08	Anaemia, chronic renal failure, cancer	Medice	aug-07
Epoetin alfa (Binocrit®)	jun-07	Anaemia, chronic renal failure, cancer	Sandoz	aug-07
Epoetin alfa (Epoetin Alfa Hexal®)	jun-07	Anaemia, chronic renal failure, cancer	Hexal	aug-07
Somatropin (Omnitrope®)	jun-03	Growth hormone deficiency, Prader-Willi syndrome, Turner syndrome, chronic renal insufficiency, small for gestational age	Sandoz	apr-06