

Approved biosimilar products in Korea

(2023.12.15.)

No.	Product name	Company	Reference product (Active ingredient)	Approval date	Withdrawal date	Remarks
1	Remsima Inj. 100mg	Celltrion, Inc	Remicade (Infliximab)	2012.07.20	–	manufacturing & marketing
2	Herzuma Inj. 150mg	Celltrion, Inc.	Herceptin (Trastuzumab)	2014.01.15	–	manufacturing & marketing
3	Herzuma Inj. 440mg	Celltrion, Inc.	Herceptin (Trastuzumab)	2014.01.15	–	manufacturing & marketing
4	SciTropin A™ Catridge 5mg	SciGen Korea Ltd	Genotropin (Somatropin)	2014.01.28	–	imported (Dev. Sandoz)
5	SciTropin A™ Catridge 10mg	SciGen Korea Ltd	Genotropin (Somatropin)	2014.01.28	–	imported
6	SciTropin A™ Catridge 15mg	SciGen Korea Ltd	Genotropin (Somatropin)	2021.07.09	–	imported
7	Davictrel Inj. 25mg	Hanwha Chemical Co.	Enbrel (Etanercept)	2014.11.11	2015.09.30	manufacturing & marketing
8	Etoloce 50mg Prefilled Syringe	Samsung Bioepis Co. Ltd	Enbrel (Etanercept)	2015.09.07	–	imported
9	Etoloce 50mg Prefilled Pen	Samsung Bioepis Co. Ltd	Enbrel (Etanercept)	2019.08.19	–	imported
10	Basaglar Cartridge 100unit/mL	Lilly Korea	Lantus (Insulin glargine)	2015.11.25	2019.06.26	imported
11	Basaglar KwikPen 100unit/mL	Lilly Korea	Lantus (Insulin glargine)	2015.11.25	–	imported
12	Remaloce Inj. 100mg	Samsung Bioepis Co. Ltd	Remicade (Infliximab)	2015.12.04	–	imported
13	Truxima Inj. 500mg	Celltrion, Inc.	Mabthera (Rituximab)	2016.11.16	–	manufacturing & marketing
14	Adaloce Prefilled Syringe Inj. 40mg	Samsung Bioepis Co. Ltd	Humira (Adalimumab)	2017.09.20	–	imported
15	Adaloce Prefilled Pen. 40mg	Samsung Bioepis Co. Ltd	Humira (Adalimumab)	2020.07.03	–	imported
16	Adaloce Prefilled Syringe Inj. 40mg/0.4mL	Samsung Bioepis Co. Ltd	Humira (Adalimumab)	2023.01.03	–	imported
17	Adaloce Prefilled Pen. 40mg 40mg/0.4mL	Samsung Bioepis Co. Ltd	Humira (Adalimumab)	2023.01.03	–	imported
18	Samfenet Inj. 150mg	Samsung Bioepis Co. Ltd	Hercetpin (Trastuzumab)	2017.11.08	–	imported
19	Samfenet Inj. 440mg	Samsung Bioepis Co. Ltd	Hercetpin (Trastuzumab)	2020.10.14	–	imported
20	Glargia Prefilled Pen	Green Cross Ltd	Lantus (Insulin glargine)	2018.03.07	–	imported
21	Eucept Prefilled Syringe Inj.	LG Chem Ltd	Enbrel (Eternercept)	2018.03.16	–	manufacturing & marketing
22	Eucept Autoinjector Inj.	LG Chem Ltd	Enbrel (Eternercept)	2018.03.16	–	manufacturing & marketing
23	Nesbell Prefilled Syringe Inj. 20	Chongkumdang	Nesp (Darbepoetin alfa)	2018.11.29	–	manufacturing & marketing

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24	Nesbell Prefilled Syringe Inj. 30	Chongkumdang	Nesp (Darbepoetin alfa)	2018.11.29	–	manufacturing & marketing
25	Nesbell Prefilled Syringe Inj. 40	Chongkumdang	Nesp (Darbepoetin alfa)	2018.11.29	–	manufacturing & marketing
26	Nesbell Prefilled Syringe Inj. 60	Chongkumdang	Nesp (Darbepoetin alfa)	2018.11.29	–	manufacturing & marketing
27	Nesbell Prefilled Syringe Inj. 120	Chongkumdang	Nesp (Darbepoetin alfa)	2018.11.29	–	manufacturing & marketing
28	Terrosa Cartridge Inj.	Daewon Pharmaceutical Co., Ltd	Posteo (Teriparatide)	2019.10.29	–	imported
29	Panpotin Prefilled Syringe Inj. 2000IU	PanGen Biotech Inc.	Epex (Epoetin alfa)	2019.11.28	–	manufacturing & marketing
30	Panpotin Prefilled Syringe Inj. 4000IU	PanGen Biotech Inc.	Epex (Epoetin alfa)	2019.11.28	–	manufacturing & marketing
31	Panpotin Prefilled Syringe Inj. 6000IU	PanGen Biotech Inc.	Epex (Epoetin alfa)	2023.08.25	–	manufacturing & marketing
32	Panpotin Prefilled Syringe Inj. 10000IU	PanGen Biotech Inc.	Epex (Epoetin alfa)	2023.08.25	–	manufacturing & marketing
33	Ogivri 150mg	Alvogen	Herceptin (Trastuzumab)	2020.08.26	2023.09.04	imported
34	Bemfola	Yooyoung Pharm.co.Ltd	Gonal-f (Follitropin alfa)	2020.10.29	–	imported
35	Onbevzi	Samsung Bioepis Co. Ltd	Avastin (Bevacizumab)	2021.03.11	–	imported
36	Zirabev	Pfizer Ltd	Avastin (Bevacizumab)	2021.05.17	–	imported
37	Yuflyma Prefilled Syringe Inj. 40mg/0.4mL	Celltrion, Inc.	Humira (Adalimumab)	2021.10.15	–	imported
38	Yuflyma Prefilled Pen Inj. 40mg/0.4mL	Celltrion, Inc.	Humira (Adalimumab)	2021.10.15	–	imported
39	Yuflyma Prefilled Syringe Inj. 80mg/0.8mL	Celltrion, Inc.	Humira (Adalimumab)	2021.10.15	–	manufacturing & marketing
40	Yuflyma Prefilled Pen Inj. 80mg/0.8mL	Celltrion, Inc.	Humira (Adalimumab)	2021.10.15	–	manufacturing & marketing
41	Bonsity	Phambio Korea. Inc.	Posteo (Teriparatide)	2021.11.16	–	imported
42	Alymsis	Alvogen	Avastin (Bevacizumab)	2022.01.19	–	imported
43	Amelivu Inj. 10mg/mL	Samsung Bioepis Co. Ltd	Lucentis (Ranibizumab)	2022.05.13	–	imported
44	Vegzelma	Celltrion, Inc.	Avastin (Bevacizumab)	2022.09.28	–	manufacturing & marketing
45	Lucenbies Inj. 10mg/mL	Chongkumdang	Lucentis (Ranibizumab)	2022.10.20	–	manufacturing & marketing
46	Lucenbies Prefilled Syringe	Chongkumdang	Lucentis (Ranibizumab)	2023.05.19	–	manufacturing & marketing

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47	Tuzepta 440mg	Samoh Pharm Co., Ltd	Hercetpin (Trastuzumab)	2023.07.10	–	imported (Dev. Biocon)
48	Tuzepta 150mg	Samoh Pharm Co., Ltd	Hercetpin (Trastuzumab)	2023.07.10	–	imported
49	Sciximab	SciGen Korea Ltd	Mabthera (Rituximab)	2023.10.27	–	imported (Dev. Sandoz)
50	TBD PFS 40mg/0.4mL	LG Chem Ltd	Humira (Adalimumab)	2023.12.14	–	manufacturing & marketing
51	TBD PFS 20mg/0.2mL	LG Chem Ltd	Humira (Adalimumab)	2023.12.14	–	manufacturing & marketing
52	TBD PFS 80mg/0.8mL	LG Chem Ltd	Humira (Adalimumab)	2023.12.14	–	manufacturing & marketing
53	TBD AI 40mg/0.4mL	LG Chem Ltd	Humira (Adalimumab)	2023.12.14	–	manufacturing & marketing