Table 1. Supplementary Information_ Database of approved liquid parenteral protein products listed alphabetically *(Last updated 18/06/2018)*

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Abasaglar (previously Abasria) (Basaglar, FDA) (1,3)	Insulin glargine	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	Zinc oxide (Zinc 30 µg/ml) Metacresol 2.7 mg/ml Glycerol 17 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=4)	09/09/2014	Eli Lilly B.V., The Netherlands
Abseamed (1)	Epoetin alfa	Hormone/Agonist/Analog	2,000, 10,000 and 40,000 IU/ml	Anemia, Chronic kidney failure, Cancer	Solution for injection (single dose)	Intravenous use or subcutaneous use	Sodium dihydrogen phosphate dihydrate Disodium phosphate dihydrate Sodium chloride Glycine Polysorbate 80 Hydrochloric acid Sodium hydroxide Water for injections	28/08/2007	Medice Arzneimittel Pütter GmbH & Co. KG, Germany
Accofil (1,2)	Filgrastim	Cytokine	600 and 960 µg/ml	Neutropenia	Solution for injection or infusion (single dose)	Subcutaneous or intravenous use	Acetic acid glacial Sodium hydroxide Sorbitol 50 mg/ml Polysorbate 80 Water for injections (pH=4)	18/09/2014	Accord Healthcare Ltd., United Kingdom
Actraphane (1)	Human insulin	Hormone/Agonist/Analog	40 and 100 IU/ml	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	Zinc chloride Glycerol Metacresol Phenol Disodium phosphate dihydrate Sodium hydroxide Hydrochloric acid Protamine sulphate Water for injections	07/10/2002	Novo Nordisk A/S, Denmark
Actrapid (1)	Human insulin	Hormone/Agonist/Analog	40 and 100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use (intravenous use if required, only by healthcare professionals)	Zinc chloride Glycerol Metacresol Sodium hydroxide Hydrochloric acid Water for injections	07/10/2002	Novo Nordisk A/S, Denmark
Aldurazyme (1,3)	Laronidase	Enzyme	100 U/ml	Mucopolysaccharidosis I	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium chloride 8.78 mg/ml Sodium phosphate monobasic monohydrate 12.7 mg/ml	10/06/2003	Genzyme Europe B.V., The Netherlands

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							Sodium phosphate dibasic heptahydrate 2.14 mg/ml Polysorbate 80 0.01 mg/ml Water for injections (pH=5.5)		
Amgevita (Amjevita, FDA) (1,2,3)	Adalimumab	Antibody (IgG1k)	50 mg/ml	Ankylosing spondylitis, Rheumatoid arthritis, Ulcerative colitis, Psoriatic arthritis, Crohn disease Psoriasis Juvenile rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Acetic acid glacial 0.6 mg/ml Sucrose 90 mg/ml Polysorbate 80 1 mg/ml Sodium hydroxide Water for injections (pH=5.2)	22/03/2017	Amgen Europe B.V., The Netherlands
Apidra (1,3)	Insulin glulisine	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous or intravenous use	Metacresol 3.15 mg/ml Sodium chloride 5 mg/ml Tris 6 mg/ml Polysorbate 20 0.01 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH= 7.3)	27/09/2004	Sanofi-Aventis Deutschland GmbH, Germany
Aranesp (1,3)	Darbepoetin alfa	Hormone/Agonist/Analog	25, 40, 60, 100, 200, 300 and 500 µg/ml	Anemia, Chronic kidney failure, Cancer	Solution for injection (single dose)	Intravenous use or subcutaneous use	Sodium phosphate monobasic 2.12 mg/ml Sodium phosphate dibasic 0.66 mg/ml Sodium chloride 8.18 mg/ml Polysorbate 80 0.05 mg/ml Water for injections (pH= 6.2±0.2)	08/06/2001	Amgen Europe B.V., The Netherlands
Arzerra (1,2,3)	Ofatumumab	Antibody (IgG1k)	20 mg/ml	Chronic b-cell lymphocytic leukemia,	Concentrate for solution for infusion (single dose)	Intravenous use	Arginine 10 mg/ml Sodium acetate 6.8 mg/ml Sodium chloride 2.98 mg/ml Polysorbate 80 0.2 mg/ml Edetate disodium (EDTA) 0.019 mg/ml Hydrochloric acid Water for injections (pH=5.5-6.5, EMA; pH=6.5 FDA)	19/04/2010	Novartis Europharm Ltd., United Kingdom
Atosiban SUN (1)	Atosiban acetate	Hormone inhibitor	7.5 mg/ml	Premature birth	Solution for injection or concentrate for solution for infusion	Intravenous use	Mannitol Hydrochloric acid Water for injections	31/07/2013	Sun Pharmaceutical Industries Europe B.V., The Netherlands

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
					(single dose)				
Avastin (1,2,3)	Bevacizumab	Antibody (IgG1)	25 mg/ml	Non-small-cell lung carcinoma, Colorectal neoplasms, Renal cell carcinoma, Ovarian neoplasms, Breast neoplasms	Concentrate for solution for infusion (single dose)	Intravenous use	EMA Trehalose dihydrate 60 mg/ml Sodium phosphate 51 mM Polysorbate 20 0.4 mg/ml Water for injections (pH=5.5) FDA Trehalose dihydrate 60 mg/ml Monobasic monohydrate 5.8 mg/ml; Dibasic dihydrate 1.2 mg/ml Polysorbate 20 0.4 mg/ml Water for injections (pH=6.2)	12/01/2005	Roche Registration Ltd., United Kingdom
Avonex (1,3)	Interferon beta-1a	Cytokine (interferon)	60 µg/ml	Multiple sclerosis	Solution for injection (single dose)	Intramuscular use	Sodium acetate trihydrate 1.58 mg/ml Acetic acid glacial 0.5 mg/ml Arginine hydrochloride 31.6 mg/ml Polysorbate 20 0.05 mg/ml Water for injections (pH=4.8)	13/03/1997	Biogen Idec Ltd., United Kingdom
Bavencio (1,3)	Avelumab	Antibody (IgG1λ)	20 mg/ml	Neuroendocrine Tumors	Concentrate for solution for infusion (single dose)	Intravenous use	Mannitol 51 mg/ml Glacial acetic acid 0.6 mg/ml Polysorbate 20 0.5 mg/ml Sodium hydroxide 0.3 mg/ml Water for injections (pH=5-5.6)	18/09/2017	Merck Serono Europe Limited
Bemfola (1,2)	Follitropin alfa	Hormone/Agonist/Analog	600 IU/ml	Anovulation	Solution for injection (single dose)	Subcutaneous use	Poloxamer 188 Sucrose 60 mg/ml Methionine 0.1 mg/ml Disodium hydrogen phosphate dihydrate 1.1 mg/ml Sodium dihydrogen phosphate dihydrate 0.52 mg/ml Phosphoric acid 0.05 ul Water for injections (pH= 6.7-7.3)	27/03/2014	Gedeon Richter Plc., Hungary
Benepali (1)	Etanercept	Fusion protein	50 mg/ml	Rheumatoid arthritis, Psoriatic arthritis, Psoriasis	Solution for injection (single dose)	Subcutaneous use	Sucrose Sodium chloride Sodium phosphate monobasic monohydrate Sodium phosphate dibasic heptahydrate	14/01/2016	Samsung Bioepis Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections (pH=6.2±0.3)		
Benlysta (1,3)	Belimumab	Antibody (IgG1λ)	80 mg/ml	Systemic lupus erythematosus	Solution for injection (single dose)	Subcutaneous use	Arginine hydrochloride 5.3 mg/ml Histidine 0.65 mg/ml Histidine hydrochloride monohydrate 1.2 mg/ml Polysorbate 80 0.1 mg/ml Sodium chloride 6.7 mg/ml Water for injections (pH=6)	13/07/2011	Glaxo Group Ltd. United Kingdom
Binocrit (1)	Epoetin alfa	Hormone/Agonist/Analog	2,000, 10,000 and 40,000 IU/ml	Anemia, Chronic kidney failure	Solution for injection (single dose)	Subcutaneous or intravenous use	Sodium dihydrogen phosphate dihydrate Disodium phosphate dihydrate Sodium chloride Glycine Polysorbate 80 Hydrochloric acid Sodium hydroxide Water for injections	28/08/2007	Sandoz GmbH, Austria
Biopoin (1)	Epoetin theta	Hormone/Agonist/Analog	2000, 4000, 6000, 8000, 10000, 20000, 30000 IU/ml	Anemia, Chronic kidney failure, Cancer	Solution for injection (single dose)	Intravenous or subcutaneous use	Sodium dihydrogen phosphate dehydrate Sodium chloride Polysorbate 20 Tris Hydrochloric acid Water for injections	23/10/2009	Teva GmbH, Germany
Blitzima (1,2)	Rituximab	Antibody (IgG1)	10 mg/ml	Non-hodgkin lymphoma, Chronic b-cell lymphocytic leukemia	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium chloride 154 mM Tri-sodium citrate dihydrate 25 mM Polysorbate 80 0.7 mg/ml Water for injections (pH=6.5)	13/07/2017	Celltrion Healthcare Kft., Hungary
Brineura (1,3)	Cerliponase alfa	Enzyme	30 mg/ml	Neuronal ceroid-lipofuscinoses	Solution for infusion (single dose)	Intra-cerebroventricular use	Sodium phosphate dibasic heptahydrate 0.11 mg/ml Sodium dihydrogen phosphate monohydrate 0.08 mg/ml Sodium chloride 8.77 mg/ml Potassium chloride 0.22 mg/ml Magnesium chloride hexahydrate 0.16 mg/ml Calcium chloride dihydrate 0.21 mg/ml Water for injections (pH=6.2-6.8)	30/05/2017	BioMarin International Ltd., Ireland

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Byetta (1,3)	Exenatide	Hormone/Agonist/Analog	0.25 mg/ml	Diabetes mellitus type 2	Solution for injection (multiple dose)	Subcutaneous use	Metacresol 2.2 mg/ml Mannitol Acetic acid glacial Sodium acetate trihydrate Water for injections (pH=4.5)	20/11/2006	AstraZeneca AB, Sweden
Cimzia (1,3)	Certolizumab pegol	Antibody (Fab fragment PEG coniugated)	200 mg/ml	Rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Sodium acetate 1.36 mg/ml Sodium chloride 7.31 mg/ml Water for injections (pH=4.7)	01/10/2009	UCB Pharma AS, Belgium
Cinqaero (Cinqair, FDA) (1,3)	Reslizumab	Antibody (IgG4k)	10 mg/ml	Asthma	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium acetate trihydrate 2.45 mg/ml Acetic acid glacial 0.12 mg/ml Sucrose 70 mg/ml Water for injections (pH=5.5)	16/08/2016	Teva Pharmaceuticals Ltd., United Kingdom
Cosentyx (1,2,3)	Secukinumab	Antibody (IgG1k)	150 mg/ml	Ankylosing spondylitis, Psoriatic arthritis, Psoriasis	Solution for injection (single dose)	Subcutaneous use	EMA Trehalose dihydrate 200 mM Histidine 20 mM Methionine 5 mM Polysorbate 80 0.2 mg/ml Water for injections (pH=5.8) FDA Trehalose dihydrate 75.67 mg/ml Histidine/Histidine hydrochloride monohydrate 3.103 mg/ml Methionine 0.746 mg/ml Polysorbate 80 0.2 mg/ml Water for injections (pH=5.8)	15/01/2015	Novartis Europharm Ltd., United Kingdom
Crysvita (1,3)	Burosumab	Antibody (IgG1)	10, 20, 30 mg/ml	Familial Hypophosphatemia, X-linked Dominant Hypophosphatemic Rickets	Solution for injection (single dose)	Subcutaneous use	Histidine 1.55 mg/ml Sorbitol 45.91 mg/ml Polysorbate 80 0.5 mg/ml Methionine 1.49 mg/ml Hydrochloric acid, 10% (for pH adjustment) Water for injections (pH=6.25)	19/02/2018	Kyowa Kirin Limited

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Cyltezo (1,3)	Adalimumab	Antibody (IgG1)	50 mg/ml	Ankylosing spondylitis, Uveitis, Rheumatoid arthritis, Suppurativa hidradenitis, Ulcerative colitis, Psoriatic arthritis, Crohn disease, Psoriasis, Juvenile rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Sodium acetate trihydrate 3 mg/ml Acetic acid glacial 0.16 mg/ml Trehalose dihydrate 81.25 mg/ml Polysorbate 80 1 mg/ml Water for injections (pH=5.2)	10/11/2017	Boehringer Ingelheim International GmbH, Germany
Cyramza (1,2,3)	Ramucirumab	Antibody (IgG1)	10 mg/ml	Stomach neoplasms	Concentrate for solution for infusion (single dose)	Intravenous use	EMA Histidine 10 mM Sodium chloride 75 mM Glycine 133 mM Polysorbate 80 0.1 mg/ml Water for injections (pH=6) FDA Histidine 0.65 mg/ml Histidine hydrochloride monohydrate 1.22 mg/ml Sodium chloride 4.38 mg/ml Glycine 9.98 mg/ml Polysorbate 80 0.1 mg/ml Water for injections (pH=6)	19/12/2014	Eli Lilly B.V., The Netherlands
Darzalex (1,3)	Daratumumab	Antibody (IgG1k)	20 mg/ml	Multiple myeloma	Concentrate for solution for infusion (single dose)	Intravenous use	Acetic acid glacial 0.18 mg/ml Mannitol 25.5 mg/ml Polysorbate 20 0.4 mg/ml Sodium acetate trihydrate 2.96 mg/ml Sodium chloride 3.5 mg/ml Water for injections (pH=5.5)	20/05/2016	Janssen-Cilag International NV, Belgium
Dupixent (1,3)	Dupilumab	Antibody (IgG4)	150 mg/ml	Dermatitis atopic	Solution for injection (single dose)	Subcutaneous use	Arginine hydrochloride 5.25 mg/ml Histidine 3.1 mg/ml Polysorbate 80 2 mg/ml Sodium acetate 1 mg/ml (pH=5.9) Acetic acid Sucrose 50 mg/ml Water for injections	27/09/2017	Sanofi-Aventis Groupe, France

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Elaprase (1,3)	Idursulfase	Enzyme	2 mg/ml	Mucopolysaccharidosis II	Concentrate for solution for infusion (single dose)	Intravenous use	Polysorbate 20 0.22 mg/ml Sodium chloride 8 mg/ml Sodium phosphate dibasic heptahydrate 0.99 mg/ml Sodium phosphate monobasic monohydrate 2.25 mg/ml Water for injections (pH=6)	08/01/2007	Shire Human Genetic Therapies AB, Sweden
Elonva (1)	Corifollitropin alfa	Hormone/Agonist/Analog	200 and 300 µg/ml	Assisted reproductive techniques, Ovulation induction	Solution for injection (single dose)	Subcutaneous use	Sodium citrate Sucrose Polysorbate 20 Methionine Sodium hydroxide Hydrochloric acid Water for injections	25/01/2010	Merck Sharp & Dohme Ltd., United Kingdom
Enbrel (1,3)	Etanercept	Fusion protein	50 mg/ml	Ankylosing spondylitis, Rheumatoid arthritis, Psoriatic arthritis, Psoriasis, Juvenile Rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Sucrose 10 mg/ml Sodium chloride 100 mM Arginine hydrochloride 25 mM Sodium phosphate monobasic dihydrate Sodium phosphate dibasic dihydrate (Sodium phosphate 25 mM) Water for injections	03/02/2000	Pfizer Ltd., United Kingdom
Epoetin Alfa Hexal (1)	Epoetin alfa	Hormone/Agonist/Analog	2,000, 10,000 and 40,000 IU/ml	Anemia, Chronic kidney failure, Cancer	Solution for injection (single dose)	Intravenous use or subcutaneous use	Sodium dihydrogen phosphate dihydrate Disodium phosphate dihydrate Sodium chloride Glycine Polysorbate 80 Hydrochloric acid Sodium hydroxide Water for injections	28/08/2007	Hexal AG, Germany
Eporatio (1)	Epoetin theta	Hormone/Agonist/Analog	2000, 4000, 6000, 8000, 10000, 20000, 30000 IU/ml;	Anemia, Chronic kidney failure, Cancer	Solution for injection (single dose)	Intravenous use or subcutaneous use	Sodium dihydrogen phosphate dihydrate Sodium chloride Polysorbate 20 Tris Hydrochloric acid Water for injections	29/10/2009	Ratiopharm GmbH, Germany
Eptifibatide Accord (1)	Eptifibatide	Antiplatelet	0.75 or 2 mg/ml	Myocardial infarction	Solution for infusion (single dose)	Intravenous use	Citric acid monohydrate Sodium hydroxide Water for injections	11/01/2016	Accord Healthcare Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Erbitux (one more strength, FDA) (1,3,4)	Cetuximab	Antibody (IgG1k)	5 mg/ml	Colorectal neoplasms, Head and neck neoplasms	Solution for infusion (single dose)	Intravenous use	Sodium chloride 100 mM Glycine 100 mM Polysorbate 80 0.1 mg/ml Citric acid monohydrate 10 mM Sodium hydroxide Water for injections pH= 5.3-5.7	29/06/2004	Merck KGaA, Germany
Erelzi (1,3)	Etanercept	Fusion protein	50 mg/ml	Ankylosing spondylitis, Rheumatoid arthritis, Psoriatic arthritis, Psoriasis Juvenile rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Citric acid anhydrous 0.79 mg/ml Sodium citrate dihydrate 13.52 mg/ml Sodium chloride 1.5 mg/ml Sucrose 10 mg/ml Lysine hydrochloride 4.6 mg/ml Sodium hydroxide Hydrochloric acid Water for injections (pH= 6.3±0.2)	23/06/2017	Sandoz GmbH, Austria
Eylea (1,3)	Aflibercept	Antiangiogenic factor	40 mg/ml	Wet macular degeneration, Macular edema, Diabetes complications	Solution for injection (single dose)	Intravitreal use	Polysorbate 20 0.3 mg/ml Sodium dihydrogen phosphate monohydrate/ Disodium hydrogen phosphate heptahydrate (Sodium phosphate) 10 mM Sodium chloride 40 mM Sucrose 50 mg/ml Water for injection (pH=6.2)	22/11/2012	Bayer AG, Germany
Fasenra (1,3)	Benralizumab	Antibody (IgG1k)	30 mg/ml	Asthma	Solution for injection (single dose)	Subcutaneous use	Histidine 1.4 mg/ml Histidine hydrochloride monohydrate 2.3 mg/ml Trehalose dihydrate 95 mg/ml Polysorbate 20 0.06 mg/ml Water for injections	08/01/2018	AstraZeneca AB
Fertavid (same composition of Puregon) (1,2,4)	Follitropin beta	Hormone/Agonist/Analog	100, 150, 200, 300, 400 and 833 IU/ml	Infertility, Hypogonadism	Solution for injection (single dose)	Subcutaneous use and intramuscular use	Sucrose 50 mg/ml Sodium citrate 14.69 mg/ml Methionine 0.5 mg/ml Polysorbate 20 0.2 mg/ml Sodium hydroxide Hydrochloric acid Water for injections (pH=7)	19/03/2009	Merck Sharp & Dohme Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Fiasp (1,3)	Insulin aspart	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous or intravenous use	Phenol Metacresol Glycerol Zinc acetate Disodium phosphate dihydrate Arginine hydrochloride Nicotinamide (vitamin B3) Hydrochloric acid Sodium hydroxide Water for injections (pH=7.1)	09/01/2017	Novo Nordisk A/S, Denmark
Filgrastim Hexal (1)	Filgrastim	Cytokine	600 and 960 µg/ml	Hematopoietic stem cell transplantation, Cancer, Neutropenia	Solution for injection or infusion (single dose)	Intravenous use or subcutaneous use	Glutamic acid Sorbitol 50 mg/ml Polysorbate 80 Water for injections	06/02/2009	Hexal AG, Germany
Flebogamma DIF (previously Flebogammadif) (Flebogamma, FDA) (1,2,3)	Human normal immunoglobulin	Antibody (Human normal immunoglobulin IVIg; containing: IgG1, IgG2, IgG3, IgG4, IgGA)	50 and 100 mg/ml	Immunologic deficiency syndromes, Guillain-barre syndrome, Bone marrow transplantation, Idiopathic thrombocytopenic purpura, Mucocutaneous lymph node syndrome	Solution for infusion (single dose)	Intravenous use	Sorbitol 50 mg/ml Water for injections PEG ≤ 3 mg/ml (reported only on the FDA source) (pH=5-6)	23/07/2007	Instituto Grifols S.A., Spain
Forsteo (Forteo, FDA) (1,3)	Teriparatide	Hormone/Agonist/Analog	250 µg/ml	Osteoporosis, Postmenopausal osteoporosis	Solution for injection (multiple dose)	Subcutaneous use	Acetic acid glacial 0.41 mg/ml Sodium acetate anhydrous 0.1 mg/ml Mannitol 45.4 mg/ml Metacresol 3 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=4)	10/06/2003	Eli Lilly B.V., The Netherlands
Gazyvaro (Gazyva, FDA) (1,3)	Obinutuzumab	Antibody (IgG1)	25 mg/ml	Chronic b-cell lymphocytic leukemia	Concentrate for solution for infusion (single dose)	Intravenous use	Histidine/ Histidine hydrochloride monohydrate 20 mM Trehalose dihydrate 240 mM Poloxamer 188 0.2 mg/ml Water for injections (pH=6)	23/07/2014	Roche Registration Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
GONAL-f (GONAL-f RFF Pen, FDA) (1,3)	Follitropin alfa	Hormone/Agonist/Analog	600 IU/ml	Anovulation Hypogonadism Female infertility Assisted reproductive techniques	Solution for injection (multiple dose)	Subcutaneous use	Poloxamer 188 0.1 mg/ml Sucrose 60 mg/ml Methionine 0.1 mg/ml Sodium dihydrogen phosphate monohydrate 0.45 mg/ml Disodium phosphate dihydrate 1.1 mg/ml Metacresol 3 mg/ml Phosphoric acid Sodium hydroxide Water for injections	20/10/1995	Merck Serono Europe Ltd., United Kingdom
Grastofil (1,4)	Filgrastim	Cytokine	600 or 960 µg/ml	Neutropenia	Solution for injection or infusion (single dose)	Subcutaneous or intravenous use	Acetic acid glacial 0.59 mg/ml Sodium hydroxide 0.035 mg/ml Sorbitol 50 mg/ml Polysorbate 80 0.08 mg/ml Water for injections (pH=4)	18/10/2013	Apotex Europe B.V., The Netherlands
Hemlibra (1,2,3)	Emicizumab	Antibody (Bispecific IgG4)	30 or 150 mg/ml	Haemophilia A	Solution for injection (single dose)	Subcutaneous use	EMA Arginine/Aspartic acid 150 mM Histidine 20 mM Poloxamer 188 Water for injections (pH=6) FDA 30 mg/ml Arginine 26.1 mg/ml Histidine 3.1 mg/ml Poloxamer 188 0.2 mg/ml Water for injections (pH=6) FDA 150 mg/ml Arginine 26.1 mg/ml Histidine 3.1 mg/ml Poloxamer 188 0.5 mg/ml Water for injections (pH=6)	23/02/2018	Roche Registration Ltd., United Kingdom
Herceptin (1,4)	Trastuzumab	Antibody (IgG1k)	120 mg/ml	Stomach neoplasms, Breast neoplasms	Solution for injection (single dose)	Subcutaneous use	Recombinant human hyaluronidase (rHuPH20) 2000IU/ml Histidine/ Histidine hydrochloride monohydrate 20 mM α,α-Trehalose dihydrate 210 mM Methionine 10 mM	28/08/2000	Roche Registration Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Polysorbate 20 0.4 mg/ml Water for injections		
Hizentra (1,2,3)	Human normal immunoglobulin (SCIg)	Antibody Human normal immunoglobulin (SCIg) 98% IgG containing IgG1, IgG2, IgG3, IgG4, IgGA)	200 mg/ml	Immunologic deficiency syndromes	Solution for injection (single dose)	Subcutaneous use	EMA Proline 250 mM Polysorbate 80 0.02 mg/ml Water for injections (pH=4.8) FDA Proline 250 mM Polysorbate 80 0.008-0.03 mg/ml Water for injections pH=4.6-5.2	14/04/2011	CSL Behring GmbH, Germany
Humalog (1,3)	Insulin lispro	Hormone/Agonist/Analog	100 and 200 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous or intravenous use (200 IU/ml is only for subcutaneous use)	100 IU/ml Metacresol 3.15 mg/ml Glycerol 16 mg/ml Dibasic sodium phosphate heptahydrate 1.88 mg/ml Zinc oxide (Zinc 0.0197 mg/ml) Water for injections Hydrochloric acid Sodium hydroxide (pH=7-7.8) 200 IU/ml Metacresol 3.15 mg/ml Glycerol 16 mg/ml Dibasic sodium phosphate heptahydrate 1.88 mg/ml Zinc oxide (Zinc 0.046 mg/ml) Tris 5 mg/ml Water for injections Hydrochloric acid Sodium hydroxide (pH=7-7.8)	30/04/1996	Eli Lilly B.V., The Netherlands
Humalog Mix 25 and Mix 50 (Humalog 75-25, Humalog 50-50, FDA) (1,3)	Insulin lispro	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	EMA Protamine sulphate 0.28 mg/ml Metacresol 1.76 mg/ml Phenol 0.80 mg/ml Glycerol 16 mg/ml Dibasic sodium phosphate heptahydrate 3.78 mg/ml Zinc oxide (Zinc 0.025 mg/ml) Water for injections Hydrochloric acid Sodium hydroxide	30/04/1996	Eli Lilly B.V., The Netherlands

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							(pH=7-7.8) <u>FDA 75-25</u> Protamine sulphate 0.28 mg/ml Metacresol 1.76 mg/ml Phenol 0.715 mg/ml Glycerol 16 mg/ml Dibasic sodium phosphate heptahydrate 3.78 mg/ml Zinc oxide (Zinc 0.025 mg/ml) Water for injections Hydrochloric acid Sodium hydroxide (pH=7-7.8) <u>FDA 50-50</u> Protamine sulphate 0.19 mg/ml Metacresol 2.20 mg/ml Phenol 0.89 mg/ml Glycerol 16 mg/ml Dibasic sodium phosphate heptahydrate 3.78 mg/ml Zinc oxide (Zinc 0.0305 mg/ml) Water for injections Hydrochloric acid Sodium hydroxide (pH=7-7.8)		
Humira (1,3)	Adalimumab	Antibody (IgG1)	50 mg/ml	Ankylosing spondylitis, Uveitis, Rheumatoid arthritis, Ulcerative colitis, Crohn disease, Psoriatic arthritis, Psoriasis, Juvenile rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Mannitol 12 mg/ml Citric acid monohydrate 1.3 mg/ml Sodium citrate 0.3 mg/ml Sodium dihydrogen phosphate dihydrate 0.85 mg/ml Disodium phosphate dihydrate 1.53 mg/ml Sodium chloride 6.18 mg/ml Polysorbate 80 1 mg/ml Sodium hydroxide Water for injections (pH=5.2)	08/09/2003	AbbVie Ltd., United Kingdom
Humira (1,3)	Adalimumab	Antibody (IgG1)	100 mg/ml	Ankylosing spondylitis, Uveitis, Rheumatoid arthritis, Ulcerative colitis, Crohn disease, Psoriatic arthritis,	Solution for injection (single dose)	Subcutaneous use	Mannitol 42 mg/ml Polysorbate 80 1 mg/ml Water for Injections (pH=5.2)	08/09/2003	AbbVie Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
				Psoriasis, Juvenile rheumatoid arthritis					
HyQvia (1,2,3)	Human normal immunoglobulin	Antibody (Human normal immunoglobulin (SCIg), 98% IgG containing IgG1, IgG2, IgG3, IgG4, IgGA)	100 mg/ml	Immunologic deficiency syndromes	Solution for infusion (single dose)	Subcutaneous use	Human normal immunoglobulin vial: Glycine 250 mM Water for injections (pH= 4.6-5.1) Recombinant human hyaluronidase (rHuPH20) vial: Recombinant human hyaluronidase 160 IU/ml Sodium chloride 8.5 mg/ml Sodium phosphate dibasic 1.78 mg/ml Human albumin 1 mg/ml Edetate disodium (EDTA) 1 mg/ml Calcium chloride 0.4 mg/ml Sodium hydroxide 0.17 mg/ml Hydrochloric acid Water for injections (pH=7.4)	16/05/2013	Baxalta Innovations GmbH, Austria
Ilaris (1,3)	Canakinumab	Antibody (IgG1k)	150 mg/ml	Cryopyrin-associated periodic syndromes, Juvenile rheumatoid arthritis, Gouty arthritis	Solution for injection (single dose)	Subcutaneous use	Mannitol 49.2 mg/ml Histidine 2.1 mg/ml Histidine hydrochloride monohydrate 1.3 mg/ml Polysorbate 80 0.4 mg/ml Water for injections	23/10/2009	Novartis Europharm Ltd., United Kingdom
Imraldi (1)	Adalimumab	Antibody (IgG1)	50 mg/ml	Ankylosing spondylitis, Arthritis, Uveitis Rheumatoid arthritis, Hidradenitis suppurativa, Ulcerative colitis, Psoriatic arthritis, Crohn disease, Psoriasis	Solution for injection (single dose)	Subcutaneous use	Sodium citrate Citric acid monohydrate Histidine Histidine hydrochloride monohydrate Sorbitol Polysorbate 20 Water for injections	24/08/2017	Samsung Bioepis Ltd., United Kingdom
Increlex (1,2,3)	Mecasermin	Growth factor	10 mg/ml	Laron syndrome	Solution for injection (multiple dose)	Subcutaneous use	Benzyl alcohol 9 mg/ml Sodium chloride 5.84 mg/ml Polysorbate 20 2 mg/ml	03/08/2007	Ipsen Pharma, France

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Acetic acid glacial Sodium acetate 50 mM Water for injections (pH= 5.4)		
Insulatard (1)	Insulin human	Hormone/Agonist/Analog	40 and 100 IU/ml	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	Zinc chloride Glycerol Metacresol Phenol Disodium phosphate dihydrate Sodium hydroxide Hydrochloric acid Protamine sulphate Water for injections	07/10/2002	Novo Nordisk A/S, Denmark
Insuman (1)	Insulin human	Hormone/Agonist/Analog	40 and 100 IU/ml	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	Protamine sulphate Metacresol Phenol Zinc chloride Sodium dihydrogen phosphate dehydrate Glycerol Sodium hydroxide Hydrochloric acid Water for injections	21/02/1997	Sanofi-Aventis Deutschland GmbH, Germany
Insuman (1)	Insulin human	Hormone/Agonist/Analog	100 or 400 IU/ml	Diabetes mellitus	Solution for infusion or injection (single or multiple dose)	Intraperitoneal and subcutaneous use	Phenol Zinc chloride Tris Poloxamer 171 Glycerol Hydrochloric acid Water for injections	21/02/1997	Sanofi-Aventis Deutschland GmbH, Germany
Insuman (1)	Insulin human	Hormone/Agonist/Analog	40 and 100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous or intravenous use	Metacresol Sodium dihydrogen phosphate dehydrate Glycerol Sodium hydroxide Hydrochloric acid Water for injections	21/02/1997	Sanofi-Aventis Deutschland GmbH, Germany
Integrilin (1,3)	Eptifibatide	Antiplatelet	0.75 mg/ml	Unstable angina, Myocardial infarction	Solution for infusion (single dose)	Intravenous use	Citric acid monohydrate 5.25 mg/ml Sodium hydroxide Water for injections (pH= 5.35)	01/07/1999	Glaxo Group Ltd., United Kingdom
Integrilin (1,3)	Eptifibatide	Antiplatelet	2 mg/ml	Unstable angina, Myocardial infarction	Solution for injection (single dose)	Intravenous use	Citric acid monohydrate 5.25 mg/ml Sodium hydroxide	01/07/1999	Glaxo Group Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections (pH= 5.35)		
IntronA (FDA product is in the lyophilised state, different excipient composition) (1,4)	Interferon alfa-2b	Cytokine (interferon)	6 million, 10 million, 15 million, 25 million, 50 million IU/ ml	Multiple myeloma, Chronic BCR-ABL positive myelogenous leukemia,, Chronic hepatitis B, Carcinoid tumor, Hairy cell leukemia, Follicular lymphoma, Melanoma Chronic hepatitis C	Solution for injection or infusion (single or multiple dose)	Intravenous use or subcutaneous use	Disodium phosphate anhydrous 1.8 mg/ml Sodium dihydrogen phosphate monohydrate 1.3 mg/ml Edetate disodium (EDTA) 0.1 mg/ml Sodium chloride 7.5 mg/ml Metacresol 1.5 mg/ml Polysorbate 80 0.1 mg/ml Water for injections	09/03/2000	Merck Sharp & Dohme Ltd., United Kingdom
Jetrea (1,3)	Ocriplasmin	Enzyme	2.5 mg/ml	Retinal diseases	Concentrate for solution for injection (single dose)	Intravitreal use	Mannitol 3.75 mg/ml Citric acid 1.05 mg/ml Sodium hydroxide Water for injections (pH=3.1)	13/03/2013	ThromboGenics NV, Belgium
Jetrea (1,3)	Ocriplasmin	Enzyme	1.25 mg/ml	Retinal diseases	Solution for injection (single dose)	Intravitreal use	Sodium chloride 4.5 mg/ml Mannitol 1.86 mg/ml Citric acid 0.53 mg/ml Sodium hydroxide Hydrochloric acid Water for injections (pH= 3.1)	13/03/2013	ThromboGenics NV, Belgium
Kanuma (1,3)	Sebelipase alfa	Enzyme	2 mg/ml	Lipid metabolism inborn errors	Concentrate for solution for infusion (single dose)	Intravenous use	Trisodium citrate dihydrate 13.7 mg/ml Citric acid monohydrate 1.57 mg/ml Human serum albumin 10 mg/ml Water for injections (pH= 5.9)	28/08/2015	Alexion Europe, France
Kevzara (1,3)	Sarilumab	Antibody (IgG1)	131.6 or 175 mg/ml	Rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Histidine 3.25 mg/ml Arginine 7.84 mg/ml Polysorbate 20 2 mg/ml Sucrose 50 mg/ml Water for injections (pH=6)	23/06/2017	Sanofi-Aventis Groupe, France
Keytruda (1,2,3)	Pembrolizumab	Antibody (IgG4k)	25 mg/ml	Non-small-cell lung carcinoma, Hodgkin disease, Melanoma	Concentrate for solution for infusion (single dose)	Intravenous use	Histidine/ Histidine hydrochloride monohydrate 1.55 mg/ml Sucrose 70 mg/ml Polysorbate 80 0.2 mg/ml	17/07/2015	Merck Sharp and Dohme Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections (pH=5.5, FDA; 5.2-5.8 EMA)		
Kineret (1,3)	Anakinra	Cytokine	150 mg/ml	Arthritis, rheumatoid	Solution for injection (single dose)	Subcutaneous use	Citric acid anhydrous 1.93 mg/ml Sodium chloride 8.18 mg/ml Edetate disodium (EDTA) dihydrate 0.18 mg/ml Polysorbate 80 1 mg/ml Sodium hydroxide Water for injections (pH=6.5)	08/03/2002	Biovitrum AB (publ), Sweden
Kiovig (1,2)	Human normal immunoglobulin (IVIg)	Antibody (human normal immunoglobulin (IVIg), 98% IgG containing IgG1, IgG2, IgG3, IgG4, IgGA)	100 mg/ml	Immunologic deficiency syndromes, Guillain-barre syndrome, Bone marrow transplantation, Purpura thrombocytopenic idiopathic. Mucocutaneous lymph node syndrome	Solution for infusion (single dose)	Intravenous use	Glycine 250 mM Water for injections (pH=4.6-5.1)	19/01/2006	Baxter AG, Austria
Kyntheum (Siliq, FDA) (1,3)	Brodalumab	Antibody (IgG2k)	140 mg/ml	Psoriasis	Solution for injection (single dose)	Subcutaneous use	Proline 24 mg/ml Glutamic acid 4.33 mg/ml Polysorbate 20 0.1 mg/ml Water for injections (pH=4.8)	17/07/2017	LEO Pharma A/S, Denmark
Lantus (1,3)	Insulin glargine	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	<u>5 ml Vial, Cartridge, Pre-filled pen</u> Zinc chloride 0.030 mg/ml Metacresol 2.7 mg/ml Glycerol 20 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=4) <u>10 ml Vial</u> Zinc chloride 0.030 mg/ml Metacresol 2.7 mg/ml Glycerol 20 mg/ml Polysorbate 20 0.020 mg/ml Hydrochlorid acid Sodium hydroxide	09/06/2000	Sanofi-Aventis Deutschland GmbH, Germany

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections (pH=4)		
Lartruvo (1,3)	Olaratumab	Antibody (IgG1)	10 mg/ml	Sarcoma	Concentrate for solution for infusion (single dose)	Intravenous use	Mannitol 13.7 mg/ml Glycine 7.5 mg/ml Sodium chloride 2.9 mg/ml Histidine hydrochloride monohydrate 1.7 mg/ml Histidine 0.3 mg/ml Polysorbate 20 0.2 mg/ml Water for injections (pH=5.2-5.8)	09/11/2016	Eli Lilly B.V., The Netherlands
Lemtrada (1,3)	Alemtuzumab	Antibody (IgG1k)	10 mg/ml	Multiple sclerosis	Concentrate for solution for infusion (single dose)	Intravenous use	Disodium phosphate dihydrate 1.15 mg/ml Edetate disodium (EDTA) dihydrate 0.02 mg/ml Potassium chloride 0.2 mg/ml Potassium dihydrogen phosphate 0.2 mg/ml Polysorbate 80 0.1 mg/ml Sodium chloride 8 mg/ml Water for injections (pH=7.2±0.2)	12/09/2013	Genzyme Therapeutics Ltd., United Kingdom
Levemir (1,3)	Insulin detemir	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	Glycerol 16 mg/ml Phenol 1.8 mg/ml Metacresol 2.06 mg/ml Zinc acetate 0.065 mg/ml Disodium phosphate dihydrate 0.89 mg/ml Sodium chloride 1.17 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=7.4)	01/06/2004	Novo Nordisk A/S, Denmark
Lifmior (same composition of Enbrel) (1,2,3)	Etanercept	Fusion protein	50 mg/ml	Ankylosing spondylitis, Psoriatic arthritis, Psoriasis	Solution for injection (single dose)	Subcutaneous use	Sucrose 10 mg/ml Sodium chloride 100 mM Arginine hydrochloride 25 mM Sodium phosphate monobasic dihydrate/ Sodium phosphate dibasic dihydrate (Sodium phosphate) 25 mM Water for injections	13/02/2017	Pfizer Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Liprolog (1)	Insulin lispro	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	Protamine sulphate Metacresol 1.76 μγ/ml Phenol 0.8 mg/ml Glycerol Dibasic sodium phosphate heptahydrate Zinc oxide Hydrochloric acid Sodium hydroxide Water for injections (pH=7-7.8)	01/08/2001	Eli Lilly B.V., The Netherlands
Liprolog (1)	Insulin lispro	Hormone/Agonist/Analog	100 and 200 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous and intravenous use (200 IU/ml is only for subcutaneous use)	Metacresol Glycerol Dibasic sodium phosphate heptahydrate Zinc oxide Hydrochloric acid Sodium hydroxide Water for injections	01/08/2001	Eli Lilly B.V., The Netherlands
Lonquex (1,2)	Lipegfilgrastim	Cytokine	10 mg/ml	Neutropenia	Solution for injection (single dose)	Subcutaneous use	Acetic acid glacial Sodium hydroxide Sorbitol Polysorbate 20 Water for injections (pH=5)	25/07/2013	Sicor Biotech UAB, Lithuania
Lucentis (1,3)	Ranibizumab	Antibody (IgG1k)	10 mg/ml	Wet macular degeneration, Macular edema, Degenerative myopia, Diabetes complications	Solution for injection (single dose)	Intravitreal use	α,α-Trehalose dihydrate 100 mg/ml Histidine hydrochloride monohydrate/ Histidine 10 mM Polysorbate 20 0.1 mg/ml Water for injections (pH=5.5)	22/01/2007	Novartis Europharm Ltd., United Kingdom
Lusduna (1)	Insulin glargine	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	Zinc chloride Metacresol Glycerol Hydrochloric acid Sodium hydroxide Water for injections	04/01/2017	Merck Sharp & Dohme Ltd., United Kingdom
Lyxumia (Adlyxin, FDA) (1,3)	Lixisenatide	Hormone/Agonist/Analog	50 and 100 μg/ml	Diabetes mellitus type 2	Solution for injection (multiple dose)	Subcutaneous use	Glycerol 85% 18 mg/ml Sodium acetate trihydrate 3.5 mg/ml Methionine 3 mg/ml Metacresol 2.7 mg/ml Hydrochloric acid	01/02/2013	Sanofi-Aventis Groupe, France

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Sodium hydroxide solution Water for injections (pH=4.5)		
MabThera (same composition of Rituxan, FDA) (1,2,3)	Rituximab	Antibody (IgG1k)	120 mg/ml	Rheumatoid arthritis, Non-hodgkin lymphoma, Chronic b-cell lymphocytic leukemia	Solution for injection (single dose)	Subcutaneous use	Recombinant human hyaluronidase (rHuPH20) 2000 IU/ml Histidine 0.53 mg/ml Histidine hydrochloride monohydrate 3.47 mg/ml α,α-Trehalose dihydrate 79.45 mg/ml Methionine 1.49 mg/ml Polysorbate 80 0.6 mg/ml Water for injections	02/06/1998	Roche Registration Ltd., United Kingdom
MabThera (same composition of Rituxan, FDA) (1,2,3)	Rituximab	Antibody (IgG1k)	10 mg/ml	Rheumatoid arthritis, Non-hodgkin lymphoma, Chronic b-cell lymphocytic leukemia	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium citrate 7.35 mg/ml Polysorbate 80 0.7 mg/ml Sodium chloride 9 mg/ml Sodium hydroxide Hydrochloric acid Water for injections (pH=6.5)	02/06/1998	Roche Registration Ltd., United Kingdom
Mircera (1,3)	Methoxy polyethylene glycol-epoetin beta	Hormone/Agonist/Analog	100, 133, 167, 200, 250, 333, 400, 500, 600, 667, 833, 1200 µg/ml	Anemia, Chronic kidney failure	Solution for injection (single dose)	Subcutaneous or intravenous use	Sodium dihydrogen phosphate monohydrate 1.38 mg/ml Sodium sulphate 5.68 mg/ml Mannitol 30 mg/ml Methionine 1.49 mg/ml Poloxamer 188 0.1 mg/ml Water for injections (pH=6.2±0.2)	20/07/2007	Roche Registration Ltd., United Kingdom
Mixtard (1)	Insulin human	Hormone/Agonist/Analog	40 and 100 IU/ml	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	Zinc chloride Glycerol Metacresol Phenol Disodium phosphate dihydrate Sodium hydroxide Hydrochloric acid Protamine sulphate Water for injections	07/10/2002	Novo Nordisk A/S, Denmark
Movymia (1)	Teriparatide	Hormone/Agonist/Analog	250 µg/ml	Osteoporosis	Solution for injection (multiple dose)	Subcutaneous use	Acetic acid glacial Mannitol Metacresol Sodium acetate trihydrate Hydrochloric acid Sodium hydroxide Water for injections	11/01/2017	STADA Arzneimittel AG, Germany

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Mvasi (1,3)	Bevacizumab	Antibody (IgG1)	25 mg/ml	Fallopian tube neoplasms, Non-small-cell lung carcinoma, Renal cell carcinoma, Ovarian neoplasms, Peritoneal neoplasms, Breast neoplasms	Concentrate for solution for infusion (single dose)	Intravenous use	Trehalose dihydrate 60 mg/ml Sodium phosphate monobasic monohydrate 5.8 mg/ml Sodium phosphate dibasic anhydrous 1.2 mg/ml Polysorbate 20 0.4 mg/ml Water for injections (pH=6.2)	15/01/2018	Amgen Europe B.V., The Netherlands
Naglazyme (1,3)	Galsulfase	Enzyme	1 mg/ml	Mucopolysaccharidosis VI	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium chloride 8.76 mg/ml Sodium phosphate monobasic monohydrate 1.24 mg/ml Sodium phosphate dibasic heptahydrate 0.268 mg/ml Polysorbate 80 0.05 mg/ml Water for injections (pH=5.8)	24/01/2006	BioMarin Europe Ltd., United Kingdom
NeoRecormon (1,4)	Epoetin beta	Hormone/Agonist/Analog	1667, 6667, 10,000, 13,333, 16,667, 20,000, 33,333, 66,667 and 50,000 IU/ml	Anemia, Autologous blood transfusion, Cancer, Chronic kidney failure	Solution for injection (single dose)	Intravenous use or subcutaneous use	Urea Sodium chloride 0.6 mg/ml Polysorbate 20 Sodium dihydrogen phosphate dehydrate Disodium phosphate dodecahydrate 10.06 mg/ml Calcium chloride dihydrate Glycine 15 mg/ml Leucine Isoleucine 2 mg/ml Threonine 0.5 mg/ml Glutamic acid Phenylalanine 0.5 mg/ml Water for injections	16/07/1997	Roche Registration Ltd., United Kingdom
Neulasta (1,3)	Pegfilgrastim	Cytokine	10 mg/ml (protein only) 20 mg/ml (including PEG)	Neutropenia, Cancer	Solution for injection (single dose)	Subcutaneous use	Sodium 0.033 mg/ml Acetate 0.58 mg/ml Sorbitol 50 mg/ml Polysorbate 20 0.033 mg/ml Water for injections (pH=4)	22/08/2002	Amgen Europe B.V., The Netherlands
NeuroBloc (Myobloc, FDA) (1,3)	Botulinum toxin type B	Toxin	5000 IU/ml	Torticollis	Solution for injection (single dose)	Intramuscular use	Disodium succinate 0.01 M Sodium chloride 0.1 M Human serum albumin 0.5 mg/ml Hydrochloric acid Water for injections (pH=5.6)	22/01/2001	Eisai Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Nivestim (same composition of Neupogen) (1,2,3)	Filgrastim	Cytokine	0.6 and 0.96 mg/ml	Neutropenia, Hematopoietic stem cell transplantation, Cancer	Solution for injection or infusion (single dose)	Intravenous use or subcutaneous use	Acetic acid glacial 0.59 mg/ml Sodium hydroxide 0.035 mg/ml Sorbitol 50 mg/ml Polysorbate 80 0.04 mg/ml Water for injections	08/06/2010	Hospira Ltd., United Kingdom
NovoMix (NovologMix 70/30 and 50/50, FDA) (1,3)	Insulin aspart	Hormone/Agonist/Analog	100 IU/ml (70 insulin aspart protamine/30 insulin aspart and 50 insulin apart protamine/50 insulin aspart)	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	70/30 Glycerol 16 mg/ml Phenol 1.50 mg/ml Metacresol 1.72 mg/ml Zinc chloride (Zinc 0.0196 mg/ml) Disodium phosphate dihydrate 1.25 mg/ml Sodium chloride 0.877 mg/ml Protamine sulphate 0.32 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=7.2-7.44) 50/50 Glycerol 16 mg/ml Phenol 1.50 mg/ml Metacresol 1.72 mg/ml Zinc chloride (Zinc 0.0196 mg/ml) Disodium phosphate dihydrate 1.25 mg/ml Sodium chloride 1.17 mg/ml Protamine sulphate 0.23 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=7.10-7.44)	01/08/2000	Novo Nordisk A/S, Denmark
NovoRapid (Novolog, FDA) (1,3)	Insulin aspart	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	Glycerol 16 mg/ml Phenol 1.50 mg/ml Metacresol 1.72 mg/ml Zinc chloride (Zinc 0.0196 mg/ml) Disodium phosphate dihydrate 1.25 mg/ml Sodium chloride 0.58 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=7.2-7.6)	07/09/1999	Novo Nordisk A/S, Denmark

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
NutropinAq (1,3)	Somatropin	Hormone/Agonist/Analog	5 mg/ml	Dwarfism pituitary, Turner syndrome	Solution for injection (multiple dose)	Subcutaneous use	Sodium chloride 8.7 mg/ml Liquified phenol 2.5 mg/ml Polysorbate 20 2 mg/ml Sodium citrate 10 mM Citric acid anhydrous Water for injections (pH=6)	16/02/2001	Ipsen Pharma, France
Ocrevus (1,2,3)	Ocrelizumab	Antibody (IgG1)	30 mg/ml	Multiple sclerosis	Concentrate for solution for infusion (single dose)	Intravenous use	EMA Sodium acetate trihydrate/Acetic acid glacial 20 mM Trehalose dihydrate 106 mM Polysorbate 20 0.2 mg/ml Water for injections (pH=5.3) FDA Sodium acetate trihydrate 2.14 mg/ml /Acetic acid glacial 0.25 mg/ml Trehalose dihydrate 40 mg/ml Polysorbate 20 0.2 mg/ml Water for injections (pH=5.3)	08/01/2018	Roche Registration Ltd., United Kingdom
Omnitrope (1,3)	Somatropin	Hormone/Agonist/Analog	3.3 mg/ml	Prader-Willi syndrome, Pituitary dwarfism, Turner syndrome	Solution for injection (multiple dose)	Subcutaneous use	Disodium hydrogen phosphate heptahydrate 8.67 mg/ml Sodium dihydrogen phosphate dihydrate 1.067 mg/ml Mannitol 35 mg/ml Poloxamer 188 2 mg/ml Benzyl alcohol 9 mg/ml Water for injections	12/04/2006	Sandoz GmbH, Austria
Omnitrope (1,3)	Somatropin	Hormone/Agonist/Analog	6.7 and 10 mg/ml	Prader-Willi syndrome, Pituitary dwarfism, Turner syndrome	Solution for injection (multiple dose)	Subcutaneous use	6.7 mg/ml Disodium hydrogen phosphate heptahydrate 1.13 mg/ml Sodium dihydrogen phosphate dihydrate 0.9 mg/ml Poloxamer 188 2 mg/ml Phenol 3 mg/ml Glycine 18.5 mg/ml Water for injections 10 mg/ml Disodium hydrogen phosphate heptahydrate 1.13 mg/ml Sodium dihydrogen phosphate dihydrate 0.9 mg/ml	12/04/2006	Sandoz GmbH, Austria

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Poloxamer 188 2 mg/ml Phenol 3 mg/ml Sodium chloride Water for injections		
Oncaspar (1,3)	Pegaspargase	Enzyme	750 IU/ml	Precursor cell lymphoblastic leukemia-lymphoma	Solution for injection/infusion (single dose)	Intravenous or intramuscular use	Sodium dihydrogen phosphate monohydrate 1.20 mg/ml Disodium phosphate heptahydrate 5.58 mg/ml Sodium chloride 8.50 mg/ml Water for injections (pH=7.3)	14/01/2016	Baxalta Innovations GmbH, Austria
Opdivo (1,3)	Nivolumab	Antibody (IgG4k)	10 mg/ml	Non-small-cell lung carcinoma, Hodgkin disease, Renal cell carcinoma, Melanoma	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium citrate dihydrate 5.88 mg/ml Sodium chloride 2.92 mg/ml Mannitol 30 mg/ml Pentetic acid 0.008 mg/ml (diethylenetriaminepentaacetic acid) Polysorbate 80 0.2 mg/ml Sodium hydroxide Hydrochloric acid Water for injections (pH=6)	19/06/2015	Bristol-Myers Squibb Pharma EEIG, United Kingdom
Orencia (1,3)	Abatacept	Fusion protein	125 mg/ml	Juvenile rheumatoid arthritis, Rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Sucrose 170 mg/ml Poloxamer 188 8 mg/ml Sodium dihydrogen phosphate monohydrate 0.285 mg/ml Disodium phosphate anhydrous 0.8375 mg/ml Water for injections (pH=6.8-7.4)	21/05/2007	Bristol-Myers Squibb Pharma EEIG, United Kingdom
Ovaleap (1,2)	Follitropin alfa	Hormone/Agonist/Analog	600 IU/ml	Anovulation	Solution for injection (multiple dose)	Subcutaneous use	Sodium dihydrogen phosphate dihydrate Sodium hydroxide Mannitol Methionine Polysorbate 20 Benzyl alcohol Benzalkonium chloride Water for injections (pH=7)	27/09/2013	Teva B.V., The Netherlands

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Ovitrelle (Ovidrel, FDA) (1,3)	Choriogonadotropin alfa	Hormone/Agonist/Analog	500 µg/ml	Anovulation, Female infertility, Assisted reproductive techniques	Solution for injection (single dose)	Subcutaneous use	Mannitol 54.56 mg/ml Methionine 0.200 mg/ml Poloxamer 188 0.100 mg/ml Phosphoric acid 0.981 mg/ml Sodium hydroxide Water for injections (pH=7±0.3, pH=6.5-7.5)	02/02/2001	Merck Serono Europe Ltd., United Kingdom
Ozempic (1,3)	Semaglutide	Hormone/Agonist/Analog	1.34 mg/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	Disodium phosphate dihydrate 1.42 mg/ml Propylene glycol 14 mg/ml Phenol 5.50 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=7.4)	08/02/2018	Novo Nordisk A/S, Denmark
Parsabiv (1,3)	Etelcalcetide hydrochloride	Peptide	5 mg/ml	Hyperparathyroidism secondary	Solution for injection (single dose)	Intravenous use	Sodium chloride 8.5 mg/ml Succinic acid 10 mM Hydrochloric acid Sodium hydroxide Water for injections (pH=3.3)	11/11/2016	Amgen Europe B.V., The Netherlands
Pegasys (1,3)	Peginterferon alfa-2a	Cytokine (interferon)	180, 270 and 360 µg/ml	Hepatitis B chronic, Hepatitis C chronic	Solution for injection (single dose)	Subcutaneous use	Sodium chloride 8 mg/ml Polysorbate 80 0.05 mg/ml Benzyl alcohol 10 mg/ml Sodium acetate 2.62 mg/ml Acetic acid 0.05 mg/ml Water for injections (pH=6±0.5)	20/06/2002	Roche Registration Ltd.., United Kingdom
Pergoveris (1)	Follitropin alfa/lutropin alfa	Hormone/Agonist/Analog	625 IU/ml (folitropin alfa) / 312.5 IU/ml (lutropin alfa)	Infertility, female	Solution for injection (multiple dose)	Subcutaneous use	Sucrose Arginine hydrochloride monohydrate Poloxamer 188 Methionine Phenol Disodium phosphate dihydrate Sodium dihydrogen phosphate monohydrate Sodium hydroxide Phosphoric acid concentrated Water for injections	25/06/2007	Merck Serono Europe Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Perjeta (1,3)	Pertuzumab	Antibody (IgG1)	30 mg/ml	Breast neoplams	Concentrate for solution for infusion (single dose)	Intravenous use	Acetic acid glacial Histidine (Histidine acetate) 20 mM Sucrose 120 mM Polysorbate 20 0.2 mg/ml Water for Injections (pH=6)	04/03/2013	Roche Registration Ltd., United Kingdom
Plegridy (1,3)	Peginterferon beta-1a	Cytokine (interferon)	126, 188 or 250 µg/ml	Multiple sclerosis	Solution for injection (single dose)	Subcutaneous use	Sodium acetate trihydrate 1.58 mg/ml Acetic acid glacial 0.5 mg/ml Arginine hydrochloride 31.6 mg/ml Polysorbate 20 0.05 mg/ml Water for injections (pH=4.8)	18/07/2014	Biogen Idec Ltd., United Kingdom
Portrazza (1,2,3)	Necitumumab	Antibody (IgG1k)	16 mg/ml	Non-small-cell lung carcinoma	Concentrate for solution for infusion (single dose)	Intravenous use	EMA Sodium citrate dihydrate/ Citric acid anhydrous 10 mM Sodium chloride 40 mM Glycine 133 mM Mannitol 50 mM Polysorbate 80 0.1 mg/ml Water for injections (pH=6) FDA Sodium citrate dihydrate 2.55 mg/ml/ Citric acid anhydrous 0.256 mg/ml Sodium chloride 2.338 mg/ml Glycine 9.984 mg/ml Mannitol 9.109 mg/ml Polysorbate 80 0.1 mg/ml Water for injections (pH=6)	15/02/2016	Eli Lilly B.V., The Netherlands
Praluent (1,3)	Alirocumab	Antibody (IgG1)	75 or 150 mg/ml	Dyslipidemias	Solution for injection (single dose)	Subcutaneous use	75 mg/ml Histidine 8 mM Sucrose 100 mg/ml Polysorbate 20 0.1 mg/ml Water for injections (pH=6) 100 mg/ml Histidine 6 mM Sucrose 100 mg/ml Polysorbate 20 0.1 mg/ml	23/09/2015	Sanofi-Aventis Groupe, France

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections (pH=6)		
Praxbind (1,3)	Idarucizumab	Antibody (Fab fragment of IgG1)	50 mg/ml	Hemorrhage	Solution for injection/infusion (single dose)	Intravenous use	Sodium acetate trihydrate 2.95 mg/ml Acetic acid 0.20 mg/ml Sorbitol 40.08 mg/ml Polysorbate 20 0.2 mg/ml Water for injections (pH=5.3-5.7)	20/11/2015	Boehringer Ingelheim International GmbH, Germany
Prialt (1,3)	Ziconotide	Peptidic analgesic	25 and 100 µg/ml	Spinal pain injections	Solution for infusion (single dose)	Intrathecal use	Methionine Sodium chloride Hydrochloric acid Sodium hydroxide Water for injections (pH=4-5)	21/02/2005	Eisai Ltd., United Kingdom
Privigen (1,2,3)	Human normal immunoglobulin (IVIg)	Antibody (Human normal immunoglobulin IVIg, IgG 98% containing IgG1, IgG2, IgG3, IgG4, IgGA)	100 mg/ml	Immunologic deficiency syndromes, Guillain-barre syndrome, Bone marrow transplantation, Purpura thrombocytopenic idiopathic, Mucocutaneous lymph node syndrome	Solution for infusion (single dose)	Intravenous use	Proline 250 mM Water for injections (pH=4.8)	25/04/2008	CSL Behring GmbH, Germany
Prolia (1,3)	Denosumab	Antibody (IgG2)	60 mg/ml	Postmenopausal osteoporosis, Bone resorption	Solution for injection (single dose)	Subcutaneous use	Acetic acid glacial Sodium hydroxide (Sodium acetate) 17 mM Sorbitol 47 mg/ml Polysorbate 20 0.1 mg/ml Water for injections (pH=5.2)	26/05/2010	Amgen Europe B.V., The Netherlands
Protaphane (1)	Insulin human	Hormone/Agonist/Analog	40 and 100 IU/ml	Diabetes mellitus	Suspension for injection (multiple dose)	Subcutaneous use	Zinc chloride Glycerol Metacresol Phenol Disodium phosphate dihydrate Sodium hydroxide Hydrochloric acid Protamine sulphate Water for injections	07/10/2002	Novo Nordisk A/S, Denmark

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Puregon (1,4)	Follitropin beta	Hormone/Agonist/Analog	100, 150, 200, 300, 400, 450, 833 IU/ml	Hypogonadism, Infertility	Solution for injection (single and multiple dose)	Subcutaneous use and intramuscular use	100, 150, 200, 300, 400, 450 IU/ml (single dose) Sucrose 50 mg/ml Sodium citrate 14.69 mg/ml Methionine 0.5 mg/ml Polysorbate 20 0.2 mg/ml Water for injections Sodium hydroxide Hydrochloric acid 833 IU/ml (multiple dose) Sucrose 50 mg/ml Sodium citrate 14.69 mg/ml Methionine 0.5 mg/ml Polysorbate 20 0.2 mg/ml Benzyl alcohol 10 mg/ml Sodium hydroxide Hydrochloric acid Water for injections (pH=7)	03/05/1996	Merck Sharp & Dohme Ltd., United Kingdom
Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta apeiron) (1,2)	Dinutuximab beta	Antibody (IgG1)	4.5 mg/ml	Neuroblastoma	Concentrate for solution for infusion (single dose)	Intravenous use	Histidine 20 mM Sucrose 50 mg/ml Polysorbate 20 0.1 mg/ml Hydrochloric acid Water for injections (pH=6±0.5)	08/05/2017	EUSA Pharma Ltd., United Kingdom
Ratiograstim (same composition of Neupogen, FDA) (1,3)	Filgrastim	Cytokine	600 µg/ml	Neutropenia, Hematopoietic stem cell transplantation, Cancer	Solution for injection or infusion (single dose)	Intravenous use or subcutaneous use	Acetic acid, glacial 0.59 mg/ml Sodium hydroxide 0.035 mg/ml Sorbitol 50 mg/ml Polysorbate 80 0.04 mg/ml Water for injections	15/09/2008	Ratiopharm GmbH, Germany
Rebif (1,3)	Interferon beta-1a	Cytokine (interferon)	44 and 88 µg/ml	Multiple sclerosis	Solution for injection (single dose)	Subcutaneous use	EMA Mannitol 54.6 mg/ml Poloxamer 188 Methionine Benzyl alcohol Sodium acetate 0.8 mg/ml Acetic acid Sodium hydroxide Water for injections FDA 44 µg/ml Mannitol 54.6 mg/ml Poloxamer 188 Methionine	04/05/1998	Merck Serono Europe Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Benzyl alcohol Sodium acetate 0.8 mg/ml Acetic acid Human serum albumin 4 mg/ml Sodium hydroxide Water for injections		
							FDA 88 µg/ml Mannitol 54.6 mg/ml Poloxamer 188 Methionine Benzyl alcohol Sodium acetate 0.8 mg/ml Acetic acid Human serum albumin 8 mg/ml Sodium hydroxide Water for injections		
Rekovelle (1)	Follitropin delta	Hormone/Agonist/Analog	33.3 µg/ml	Anovulation	Solution for injection (multiple dose)	Subcutaneous use	Phenol Polysorbate 20 Methionine Sodium sulphate decahydrate Disodium phosphate dodecahydrate Phosphoric acid concentrated Sodium hydroxide Water for injections	12/12/2016	Ferring Pharmaceuticals A/S, Denmark
Repatha (1,3)	Evolocumab	Antibody (IgG2)	120 or 140 mg/ml	Dyslipidemias, Hypercholesterolemia	Solution for injection (single dose)	Subcutaneous use	Proline 25 mg/ml Acetic acid glacial/Sodium hydroxide (Sodium acetate) 1.2 mg/ml Polysorbate 80 0.1 mg/ml Water for injections (pH=5)	17/07/2015	Amgen Europe B.V., The Netherlands
Replagal (1)	Agalsidase alfa	Enzyme	1 mg/ml	Fabry disease	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium phosphate monobasic monohydrate Polysorbate 20 Sodium chloride Sodium hydroxide Water for injections (pH=6±0.5)	03/08/2001	Shire Human Genetic Therapies AB, Sweden

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Retacrit (more strenghts, FDA) (1,3)	Epoetin zeta	Hormone/Agonist/Analog	3,333; 10,000 and 40,000 IU/ml	Anemia Chronic kidney failure, Autologous blood transfusion, Cancer	Solution for injection (single dose)	Intravenous use or subcutaneous use	3,333,10,000 IU/ml Disodium phosphate dihydrate 4.9 mg/ml Sodium dihydrogen phosphate dihydrate 1.3 mg/ml Sodium chloride 2.4 mg/ml Calcium chloride dihydrate 0.01 mg/ml Polysorbate 20 0.1 mg/ml Glycine 7.5 mg/ml Leucine 1 mg/ml Isoleucine 1 mg/ml Threonine 0.25 mg/ml Glutamic acid 0.25 mg/ml Phenylalanine 0.25 mg/ml Sodium hydroxide Hydrochloric acid Water for injections 40,000 IU/ml Disodium phosphate dihydrate 5.7 mg/ml Sodium dihydrogen phosphate dihydrate 1.5 mg/ml Sodium chloride 2.2 mg/ml Calcium chloride dihydrate 0.01 mg/ml Polysorbate 20 0.1 mg/ml Glycine 7.5 mg/ml Leucine 1 mg/ml Isoleucine 1 mg/ml Threonine 0.25 mg/ml Glutamic acid 0.25 mg/ml Phenylalanine 0.25 mg/ml Sodium hydroxide Hydrochloric acid Water for injections	18/12/2007	Hospira Ltd., United Kingdom
Ritemvia (1,2)	Rituximab	Antibody (IgG1k)	10 mg/ml	Wegener granulomatosis, Microscopic polyangiitis, Non-hodgkin lymphoma	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium chloride 154 mM Tri-sodium citrate dihydrate 25 mM Polysorbate 80 0.7 mg/ml Water for injections (pH=6.5)	13/07/2017	Celltrion Healthcare Kft., Hungary

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Rituzena (previously Tuxella) (1,2)	Rituximab	Antibody (IgG1k)	10 mg/ml	Wegener granulomatosis, Microscopic polyangiitis, Non-hodgkin lymphoma, Chronic b-cell lymphocytic leukemia	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium chloride 154 mM Tri-sodium citrate dihydrate 25 mM Polysorbate 80 0.7 mg/ml Water for injections (pH=6.5)	13/07/2017	Celltrion Healthcare Kft., Hungary
Rixathon (1)	Rituximab	Antibody (IgG1k)	10 mg/ml	Wegener granulomatosis, Microscopic polyangiitis, Rheumatoid arthritis, Non-hodgkin lymphoma, Chronic b-cell lymphocytic leukemia	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium citrate Polysorbate 80 Sodium chloride Sodium hydroxide Hydrochloric acid Water for injections	15/06/2017	Sandoz GmbH, Austria
Riximyo (1)	Rituximab	Antibody (IgG1k)	10 mg/ml	Wegener granulomatosis, Microscopic polyangiitis, Rheumatoid arthritis, Non-hodgkin lymphoma	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium citrate Polysorbate 80 Sodium chloride Sodium hydroxide Hydrochloric acid Water for injections	15/06/2017	Sandoz GmbH, Austria
RoActemra (Actemra, FDA) (1)	Tocilizumab	Antibody (IgG1k)	180 mg/ml	Juvenile rheumatoid arthritis, Rheumatoid arthritis	Solution for injection (single dose)	Subcutaneous use	Histidine Histidine hydrochloride monohydrate Arginine Arginine hydrochloride Methionine Polysorbate 80 Water for injections	16/01/2009	Roche Registration Ltd., United Kingdom
RoActemra (Actemra, FDA) (1,3)	Tocilizumab	Antibody (IgG1k)	20 mg/ml	Juvenile rheumatoid arthritis, Rheumatoid arthritis	Concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Polysorbate 80 0.5 mg/ml Disodium phosphate dodecahydrate Sodium dihydrogen phosphate dihydrate (Sodium phosphate) 15 mM Water for injections (pH=6.5)	16/01/2009	Roche Registration Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Ryzodeg (1,3)	Insulin degludec / insulin aspart	Hormone/Agonist/Analog	100 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	Glycerol 19 mg/ml Metacresol 1.72 mg/ml Phenol 1.50 mg/ml Sodium chloride 0.58 mg/ml Zinc acetate (Zinc 0.0274 mg/ml) Hydrochloric acid Sodium hydroxide Water for injections (pH=7.4)	21/01/2013	Novo Nordisk A/S, Denmark
Saxenda (1,3)	Liraglutide	Hormone/Agonist/Analog	6 mg/ml	Overweight, Obesity	Solution for injection (multiple dose)	Subcutaneous use	Disodium phosphate dihydrate 1.42 mg/ml Propylene glycol 14 mg/ml Phenol 5.5 mg/ml Hydrochloric acid Sodium hydroxide Water for injections	23/03/2015	Novo Nordisk A/S, Denmark
Semglee (same composition of Lantus) (1,2,3)	Insulin glargine	Hormone/Agonist/Analog	100 IU/ml	Diabetes Mellitus, type 2	Solution for injection (multiple dose)	Subcutaneous use	Zinc chloride 0.030 mg/ml Metacresol 2.7 mg/ml Glycerol 20 mg/ml Hydrochloric acid Sodium hydroxide Water for injections	23/03/2018	Mylan S.A.S
Silapo (1)	Epoetin zeta	Hormone/Agonist/Analog	3,333, 10,000 and 40,000 IU/ml	Anemia Chronic kidney failure, Autologous blood transfusion, Cancer	Solution for injection (single dose)	Intravenous use or subcutaneous use	Disodium phosphate dehydrate Sodium dihydrogen phosphate dehydrate Sodium chloride Calcium chloride dihydrate Polysorbate 20 Glycine Leucine Isoleucine Threonine Glutamic acid Phenylalanine Sodium hydroxide Hydrochloric acid Water for injections	18/12/2007	Stada Arzneimittel AG, Germany
Simponi (1,3)	Golimumab	Antibody (IgG1)	100 mg/ml	Ankylosing spondylitis, Rheumatoid arthritis, Ulcerative colitis, Psoriatic arthritis	Solution for injection (single dose)	Subcutaneous use	Sorbitol 41 mg/ml Histidine/ Histidine hydrochloride monohydrate 0.87 mg/ml Polysorbate 80 0.16 mg/ml Water for injections (pH=5.5)	01/10/2009	Janssen Biologics B.V.

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Soliris (1,3)	Eculizumab	Antibody (IgG2/4k)	10 mg/ml	Paroxysmal haemoglobinuria	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium phosphate monobasic 0.46 mg/ml Sodium phosphate dibasic 1.78 mg/ml Sodium chloride 8.77 mg/ml Polysorbate 80 0.22 mg/ml Water for injections (pH=7)	20/06/2007	Alexion Europe SAS, France
Solymbic (same composition of Amjevita, FDA) (1,3)	Adalimumab	Antibody (IgG1)	50 mg/ml	Ankylosing spondylitis, Rheumatoid arthritis, Hidradenitis suppurativa Ulcerative colitis, Psoriatic arthritis, Crohn disease, Psoriasis	Solution for injection (single dose)	Subcutaneous use	Acetic acid glacial 0.6 mg/ml Sucrose 90 mg/ml Polysorbate 80 1 mg/ml Sodium hydroxide Water for injections (pH=5.2)	22/03/2017	Amgen Europe B.V. The Netherlands
Stelara (1,3)	Ustekinumab	Antibody (IgG1k)	90 mg/ml	Psoriatic arthritis, Crohn disease, Psoriasis	Solution for injection (single dose)	Subcutaneous use	Histidine/ Histidine hydrochloride monohydrate 1 mg/ml Polysorbate 80 0.04 mg/ml Sucrose 76 mg/ml Water for injections (pH=5.7-6.3)	16/01/2009	Janssen-Cilag International NV, Belgium
Stelara (1,3)	Ustekinumab	Antibody (IgG1k)	5 mg/ml	Psoriatic arthritis, Crohn disease, Psoriasis	Concentrate for solution for infusion (single dose)	Intravenous use	Edetate disodium (EDTA) dihydrate 0.02 mg/ml Histidine 0.77 mg/ml Histidine hydrochloride monohydrate 1.04 mg/ml Methionine 0.4 mg/ml Polysorbate 80 0.4 mg/ml Sucrose 85 mg/ml Water for injection (pH=5.7-6.3)	16/01/2009	Janssen-Cilag International NV, Belgium
Strensiq (1,3)	Asfotase alfa	Enzyme	40 or 100 mg/ml	Hypophosphatasia	Solution for injection (single dose)	Subcutaneous use	Sodium chloride 8.76 mg/ml Sodium phosphate dibasic heptahydrate 5.5 mg/ml Sodium phosphate monobasic monohydrate 0.62 mg/ml Water for injections (pH=7.2-7.6)	28/08/2015	Alexion Europe SAS, France
Suliqua (Soliqua, FDA) (1,3)	Insulin glargine/ lixisenatide	Hormone/Agonist/Analog	100 IU/ml (insulin glargine) / 50µg/ml	Diabetes mellitus type 2	Solution for injection (multiple dose)	Subcutaneous use	Glycerol 85% 20 mg/ml Methionine 3 mg/ml Metacresol 2.7 mg/ml	11/01/2017	Sanofi-Aventis Groupe, France

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
			(lixisenatide) and 100 IU/ml (insulin glargine) / 33µg/ml (lixisenatide)				Zinc chloride (Zinc 0.030 mg/ml) Hydrochloric acid Sodium hydroxide Water for injections		
Synagis (1,3)	Palivizumab	Antibody (IgG1k)	100 mg/ml	Respiratory syncytial virus infections	Solution for injection (single dose)	Intramuscular use	Histidine 3.9 mg/ml Glycine 0.1 mg/ml Chloride 0.5 mg/ml (only for the FDA product) Water for injections (pH=6)	13/08/1999	AbbVie Ltd., United Kingdom
Taltz (1,3)	Ixekizumab	Antibody (IgG4)	80 mg/ml	Psoriasis	Solution for injection (single dose)	Subcutaneous use	Sodium citrate 5.11 mg/ml Citric acid anhydrous 0.51 mg/ml Sodium chloride 11.69 mg/ml Polysorbate 80 0.3 mg/ml Water for injections (pH=5.3-6.1)	25/04/2016	Eli Lilly B.V., The Netherlands
Tecentriq (1,2,3)	Atezolizumab	Antibody (IgG1k)	60 mg/ml	Non-small-cell lung carcinoma, Transitional cell carcinoma	Concentrate for solution for infusion (single dose)	Intravenous use	EMA Histidine 20 mM Acetic acid glacial Sucrose 120 mM Polysorbate 20 0.4 mg/ml Water for injections (pH=5.8) FDA Histidine 3.1 mg/ml Acetic acid glacial 0.825 mg/ml Sucrose 41.08 mg/ml Polysorbate 20 0.4 mg/ml Water for injections (pH=5.8)	21/09/2017	Roche Registration Ltd., United Kingdom
Tevagrastim (same composition of Neupogen, FDA) (1,2,3)	Filgrastim	Cytokine	600 µg/ml	Neutropenia, Hematopoietic stem cell transplantation, Cancer	Solution for injection or infusion (single dose)	Intravenous use or subcutaneous use	Acetic acid, glacial 0.59 mg/ml Sodium hydroxide 0.035 mg/ml Sorbitol 50 mg/ml Polysorbate 80 0.04 mg/ml Water for injections	15/09/2008	Teva GmbH, Germany
Toujeo (previously Optisulin) (1,3)	Insulin glargine	Hormone/Agonist/Analog	100 and 300 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	100, 300 IU/ml 5 ml Vial Zinc chloride (Zinc 0.090 mg/ml) Metacresol 2.7 mg/ml Glycerol 85% 20 mg/ml Hydrochloric acid	27/06/2000	Sanofi-Aventis Deutschland GmbH, Germany

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Sodium hydroxide Water for injections (pH=4)		
							100 IU/ml 10 ml Vial Zinc chloride (Zinc 0.090 mg/ml) Metacresol 2.7 mg/ml Glycerol 85% 20 mg/ml Polysorbate 20 Hydrochloric acid Sodium hydroxide Water for injections (pH=4)		
Tractocile (1,2)	Atosiban acetate	Hormone inhibitor	7.5 mg/ml	Premature birth	Concentrate for solution for infusion or solution for injection (single dose)	Intravenous use	Mannitol 50 mg/ml Hydrochloric acid 1M Water for injections (pH=4.5)	20/01/2000	Ferring Pharmaceuticals A/S, Denmark
Tremfya (1,3)	Guselkumab	Antibody (IgG1λ)	100 mg/ml	Psoriasis	Solution for injection (single dose)	Subcutaneous use	Histidine 0.6 mg/ml Histidine hydrochloride monohydrate 1.5 mg/ml Polysorbate 80 0.5 mg/ml Sucrose 79 mg/ml Water for injections (pH=5.8)	10/11/2017	Janssen-Cilag International NV, Belgium
Tresiba (1,3)	Insulin degludec	Hormone/Agonist/Analog	100 and 200 IU/ml	Diabetes mellitus	Solution for injection (multiple dose)	Subcutaneous use	100 IU/ml Glycerol 19.6 mg/ml Metacresol 1.72 mg/ml Phenol 1.50 mg/ml Zinc acetate 0.0327 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=7.6)	21/01/2013	Novo Nordisk A/S, Denmark
							200 IU/ml Glycerol 19.6 mg/ml Metacresol 1.72 mg/ml Phenol 1.50 mg/ml Zinc acetate 0.0719 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH=7.6)		

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Trulicity (1,3)	Dulaglutide	Hormone/Agonist/Analog	1.5 or 3 mg/ml	Diabetes mellitus, type 2	Solution for injection (single dose)	Subcutaneous use	Sodium citrate 2.74 mg/ml Citric acid anhydrous 0.14 mg/ml Mannitol 46.4 mg/ml Polysorbate 80 0.2 mg/ml Water for injections	21/11/2014	Eli Lilly B.V., The Netherlands
Truxima (1,2)	Rituximab	Antibody (IgG1k)	10 mg/ml	Wegener granulomatosis, Microscopic polyangiitis, Rheumatoid arthritis, Non-hodgkin lymphoma, Chronic b-cell lymphocytic leukemia	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium chloride 154 mM Tri-sodium citrate dihydrate 25 mM Polysorbate 80 0.7 mg/ml Water for injections (pH=6.5)	17/02/2017	Celltrion Healthcare Kft., Hungary
Tysabri (1,3)	Natalizumab	Antibody (IgG4k)	20 mg/ml	Multiple sclerosis	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium phosphate monobasic monohydrate 1.13 mg/ml Sodium phosphate dibasic heptahydrate 0.48 mg/ml Sodium chloride 8.2 mg/ml Polysorbate 80 0.2 mg/ml Water for injections (pH=6.1)	27/06/2006	Biogen Idec Ltd., United Kingdom
Vectibix (1,3)	Panitumumab	Antibody (IgG2k)	20 mg/ml	Colorectal neoplasms	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium chloride 5.8 mg/ml Sodium acetate trihydrate 6.8 mg/ml Acetic acid glacial Water for injections (pH=5.6-6)	03/12/2007	Amgen Europe B.V., The Netherlands
Victoza (1,3)	Liraglutide	Hormone/Agonist/Analog	6 mg/ml	Diabetes mellitus type 2	Solution for injection (multiple dose)	Subcutaneous use	Disodium phosphate dihydrate 1.42 mg/ml Propylene glycol 14 mg/ml Phenol 5.5 mg/ml Water for injections	30/06/2009	Novo Nordisk A/S, Denmark
Vimizim (1,3)	Elosulfase alfa (Recombinant human n-acetylgalactosamine-6-sulfatase (rhgalns)	Enzyme	1 mg/ml	Mucopolysaccharidosis IV	Concentrate for solution for infusion (single dose)	Intravenous use	Sodium acetate trihydrate 2.72 mg/ml Monosodium phosphate monohydrate 6.9 mg/ml Arginine hydrochloride 6.32 mg/ml Sorbitol 20 mg/ml Polysorbate 20 0.1 mg/ml Water for injections (pH=5-5.8)	28/04/2014	BioMarin Europe Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Xgeva (1,3)	Denosumab	Antibody (IgG2)	70 mg/ml	Neoplasm metastasis, Bone fractures	Solution for injection (single dose)	Subcutaneous use	Acetic acid glacial Sodium hydroxide (Sodium acetate 18 mM) Sorbitol 46 mg/ml Polysorbate 20 0.1 mg/ml Water for injections (pH=5.2)	13/07/2011	Amgen Europe B.V., The Netherlands
Xolair (1,4)	Omalizumab	Antibody (IgG1k)	150 mg/ml	Urticaria, Asthma	Solution for injection (single dose)	Subcutaneous use	Arginine hydrochloride 42.10 mg/ml Histidine hydrochloride 2.34 mg/ml Histidine 1.37 mg/ml Polysorbate 20 0.40 mg/ml Water for injections	25/10/2005	Novartis Europharm Ltd., United Kingdom
Xultophy (1,3)	Insulin degludec / liraglutide	Hormone/Agonist/Analog	100 IU/ml (insulin) / 3.6 mg/ml (liraglutide)	Diabetes mellitus type 2	Solution for injection (multiple dose)	Subcutaneous use	Glycerol 19.7 mg/ml Phenol 5.7 mg/ml Zinc acetate (Zinc 0.055 mg/ml) Hydrochloric acid Sodium hydroxide Water for injections (pH=8.15)	18/09/2014	Novo Nordisk A/S, Denmark
Yervoy (1,3)	Ipilimumab	Antibody (IgG1k)	5 mg/ml	Melanoma	Concentrate for solution for infusion (single dose)	Intravenous use	Tris hydrochloride 3.15 mg/ml Sodium chloride 5.85 mg/ml Mannitol 10 mg/ml Pentetic acid 0.04 mg/ml (diethylenetriaminepenta-acetic acid) Polysorbate 80 0.1 mg/ml Sodium hydroxide Hydrochloric acid Water for injections (pH=7)	13/07/2011	Bristol-Myers Squibb Pharma EEIG, United Kingdom
Zaltrap (1,3)	Aflibercept	Antiangiogenic factor	25 mg/ml	Colorectal neoplasms	Concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 200 mg/ml Sodium chloride 100 mM Sodium citrate dihydrate Citric acid monohydrate (Sodium citrate 5 mM) Polysorbate 20 1 mg/ml Sodium phosphate dibasic heptahydrate Sodium phosphate monobasic monohydrate (Sodium phosphate 5 mM) Sodium hydroxide	01/02/2013	Sanofi-Aventis Groupe, France

Commercial name	API	Type of protein	API quantitative com\position	Therapeutic area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Hydrochloric acid Water for injections (pH=6.2)		
Zarzio (Zarxio, FDA) (1,3)	Filgrastim	Cytokine	600 and 960 µg/ml	Hematopoietic Stem cell transplantation, Cancer, Neutropenia	Solution for injection or infusion (single dose)	Intravenous use or subcutaneous use	Glutamic acid 1.472 mg/ml Sorbitol 50 mg/ml Polysorbate 80 0.04 mg/ml Water for injections	06/02/2009	Sandoz GmbH, Austria
Zinplava (1,3)	Bezlotoxumab	Antibody (IgG1)	25 mg/ml	Enterocolitis pseudomembranous	Concentrate for solution for infusion (single dose)	Intravenous use	Citric acid monohydrate 0.8 mg/ml Pentetic acid (diethylenetriaminepenta-acetic acid) 0.0078 mg/ml Polysorbate 80 0.25 mg/ml Sodium chloride 8.77 mg/ml Sodium citrate dihydrate 4.75 mg/ml Sodium hydroxide Water for injections (pH=6)	18/01/2017	Merck Sharp&Dohme Ltd., United Kingdom
Zutectra (1)	Human hepatitis-B immunoglobulin	Antibody (Human normal immunoglobulin+ Hepatitis B virus surface antigen (HBs) (containing IgG1, IgG2, IgG3, IgG4, IgGA)	500 IU/ml	Passive immunization, Hepatitis B, Liver transplantation	Solution for injection (single dose)	Subcutaneous use	Glycine Water for injections	30/11/2009	Biotest Pharma GmbH, Germany

Note: 'Conflicting or additional information for products with the same name may be available when consulting different information sources. This database is a snapshot of the information acquired for selected products approved in the European Union in the timeframe specified. Authors guarantee the reliability of the informa tion which are double checked against the primary sources listed below. Primary sources are dynamic and therefore a certain variability in the information availability could be observed over time'

1. EMA. European public assessment reports (EPAR) for human medicines published by the European Medicines Agency (EMA). 1995 [updated 18/06/2018. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124.
2. EMA. Scientific Discussion, Assesment history, EPAR 2018 [updated 18/06/2018. Available from: www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003766.
3. FDA. FDA Drugs [updated 18/06/2018. Available from: https://www.fda.gov/Drugs/default.htm.
4. Marketing Authorisation Holder. Product Information. 2018.