Table 2. Supplementary Information_ Database of approved lyophilised parenteral protein products listed alphabetically *(Last updated 18/06/2018)*

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Adcetris (1,2,3)	Brentuximab vedotin	Antibody-drug conjugate (ADC) (IgG1)	5 mg/ml (50 mg/vial)	Hodgkin disease, Non-Hodgkin lymphoma	Powder for concentrate for solution for infusion (single dose)	Intravenous use	EMA Trehalose dihydrate 63 mg/ml Sodium citrate dihydrate/Citric acid monohydrate 20 mM Polysorbate 80 0.2 mg/ml (pH= 6.6) FDA Trehalose dihydrate 70 mg/ml Sodium citrate dihydrate 5.6 mg/ml Citric acid monohydrate 0.21 mg/ml Polysorbate 80 0.2 mg/ml (pH= 6.6)	25/10/2012	Takeda Pharma A/S, Denmark
Advate (1,3)	Octocog alfa	Coagulation factor (antihaemophilic)	50, 100, 125, 200, 250, 300, 400, 500, 600, 750 IU/ml (250,500,1000,1500,2000, 3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	50,100,200,300,400,600 IU/ml Powder: Mannitol 32 mg/ml Sodium chloride 90 mM Histidine 10 mM Trehalose 8 mg/ml Calcium chloride 1.7 mM Tris 10 mM Polysorbate 80 0.1 mg/ml Glutathione (reduced) 0.08 mg/ml Solvent: Water for injections 125,250,500,750 IU/ml Powder: Mannitol 80 mg/ml Sodium chloride 225 mM Histidine 25 mM Trehalose 20 mg/ml Calcium chloride 4.2 mM Tris 25 mM Polysorbate 80 0.25 mg/ml Glutathione (reduced) 0.2 mg/ml Solvent: Water for injections	02/03/2004	Baxter AG, Austria

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Adynovi (Adynovate, FDA) (1,3)	Rurioctocog alfa pegol	Coagulation factor	50, 100, 125, 200, 250, 400, 500 IU/ml (250,500,1000,2000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Mannitol 32 mg/ml Trehalose dihydrate 8 mg/ml Histidine 1.56 mg/ml Glutathione 0.008 mg/ml Sodium chloride 5.26 mg/ml Calcium chloride dihydrate 0.24 mg/ml Tris 1.22 mg/ml Polysorbate 80 0.1 mg/ml Solvent: Water for injections	08/01/2018	Baxalta Innovations GmbH, Austria
Afstyla (1,3)	Lonoctocog alfa	Coagulation factor	100, 200, 300, 400, 500, 600 IU/ml (250,500,1000,1500,2000, 2500,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Histidine 3.1 mg/ml Polysorbate 80 0.2 mg/ml Calcium chloride dehydrate 0.4 mg/ml Sodium chloride 16.4 mg/ml Sucrose 6 mg/ml Solvent: Water for injections	04/01/2017	CSL Behring GmbH, Germany
Alprolix (1,3)	Eftrenonacog alfa	Coagulation factor	50, 100, 200, 400 or 600 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia B	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose Histidine Mannitol Polysorbate 20 Sodium hydroxide Hydrochloric acid Solvent: Sodium chloride Water for injections	12/05/2016	Swedish Orphan Biovitrum AB (publ), Sweden
Angiox (Angiomax, FDA) (1,3)	Bivalirudin	Anticoagulant	50 mg/ml (250 mg/vial)	Acute coronary syndrome	Powder for concentrate for solution for injection or infusion (single dose)	Intravenous use	Mannitol 25 mg/ml Sodium hydroxide (pH=5-6)	20/09/2004	The Medicines Company Ltd., United Kingdom
ATryn (1,2)	Antithrombin alfa	Antithrombin	175 IU/ml (1750 IU/vial)	Antithrombin III deficiency	Powder for solution for infusion (single dose)	Intravenous use	Glycine 133 mM Sodium citrate 135 mM Sodium chloride 10 mM (pH=7)	28/07/2006	Laboratoire Francais du Fractionnement et des Biotechnologies

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Avonex (1,3)	Interferon beta-1a	Cytokine (interferon)	30 µg/ml (30 µg/vial)	Multiple sclerosis	Powder and solvent for solution for injection (single dose)	Intramuscular use	Powder: Human serum albumin 15 mg/ml Dibasic sodium phosphate 5.7 mg/ml Monobasic sodium phosphate 1.2 mg/ml Sodium chloride 5.8 mg/ml (pH=7.3) Solvent: Water for injections	13/03/1997	Biogen Idec Ltd., United Kingdom
BeneFIX (1,2,3)	Nonacog alfa	Coagulation factor (antihaemophylic)	50, 100, 200, 300, 400, 600 IU/ml (250,500,1000,1500,2000, 3000 IU/vial)	Haemophilia B	Powder and solvent for solution for injection (single dose)	Intravenous use	EMA Powder: Sucrose 10 mg/ml Glycine 260 mM Histidine 10 mM Polysorbate 80 0.05 mg/ml Solvent: Sodium chloride solution FDA Powder: Sucrose 8 mg/ml Glycine 208 mM Histidine 8 mM Polysorbate 80 0.04 mg/ml (pH= 6.8) Solvent: Sodium chloride solution 2.34 mg/ml	27/08/1997	Pfizer Ltd., United Kingdom
Benlysta (1,3)	Belimumab	Antibody (IgG1λ)	80 mg/ml (120 or 400 mg/vial)	Systemic lupus erythematosus	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Citric acid monohydrate 0.16 mg/ml Sodium citrate 2.7 mg/ml Sucrose 80 mg/ml Polysorbate 80 0.4 mg/ml (pH=6.5)	13/07/2011	Glaxo Group Ltd., United Kingdom
Beromun (1)	Tasonermin	Cytokine	0.2 mg/ml (1 mg/vial)	Sarcoma	Powder and solvent for solution for infusion (single dose)	Intraarterial use	Powder: Sodium dihydrogen phosphate dihydrate Disodium phosphate dodecahydrate Human serum albumin Solvent: Sodium chloride Water for injections	13/04/1999	Boehringer Ingelheim International GmbH, Germany
Besponsa (1,3)	Inotuzumab ozogamicin	Antibody-drug conjugate (ADC) (IgG4k)	0.25 mg/ml (1 mg/vial)	Precursor cell lymphoblastic leukemia-lymphoma	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Polysorbate 80 0.1 mg/ml Sodium chloride 0.6 mg/ml Tris 2.4 mg/ml (pH=8)	29/06/2017	Pfizer Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Betaferon (Betaseron, FDA) (1,3)	Interferon beta-1b	Cytokine (interferon)	0.25 mg/ml (0.30 mg/vial)	Multiple sclerosis	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Human albumin 12.5 mg/ml Mannitol 12.5 mg/ml Solvent: Sodium chloride 5.4 mg/ml Water for injections	30/11/1995	Bayer AG, Germany
Blincyto (1,3)	Blinatumomab	Antibody (Bispecific)	12.5 µg/ml (38.5 µg/vial)	Precursor cell lymphoblastic leukemia-lymphoma	Powder for concentrate and solution for solution for infusion (single dose)	Intravenous use	Powder: Citric acid monohydrate 1.20 mg/ml Trehalose dihydrate 34.11 mg/ml Lysine hydrochloride 8.30 mg/ml Polysorbate 80 0.23 mg/ml Sodium hydroxide Solution: Citric acid monohydrate Lysine hydrochloride Polysorbate 80 Sodium hydroxide Water for injections (pH=7)	23/11/2015	Amgen Europe B.V., The Netherlands
Ceprotin (1,3)	Human protein C	Coagulation factor	100 IU/ml (500 or 1000 IU/vial)	Protein C deficiency, Purpura fulminans	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Human albumin 8 mg/ml Sodium chloride 8.8 mg/ml Trisodium citrate dihydrate 4.4 mg/ml Solvent: Sterilised water for injections (pH=6.7-7.3)	16/07/2001	Baxter AG, Austria
Cerezyme (1,3)	Imiglucerase	Enzyme	40 units/ml (1 mg/ml) (200 or 400 IU/vial)	Gaucher disease	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Mannitol 32.07 mg/ml Sodium citrate 13.2 mg/ml Citric acid monohydrate Polysorbate 80 0.1 mg/ml (pH=6.1)	17/11/1997	Genzyme Europe BV, The Netherlands
Cetrotide (another strength, FDA) (1,3)	Cetrorelix	Hormon (GnRh antagonist)	0.25 mg/ml (0.25 mg/vial)	Ovulation, Induction ovulation	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Mannitol 54.8 mg/ml Solvent: Water for injections (pH=5-8)	13/04/1999	Merck Serono Europe Ltd., United Kingdom
Cinryze (1,3)	C1 inhibitor (human)	Enzyme inhibitor	100 IU/ml (500 IU/vial)	Hereditary angioedemas	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sodium chloride 4.1 mg/ml Sucrose 21 mg/ml Trisodium citrate 2.6 mg/ml Valine 2 mg/ml Alanine 1.2 mg/ml Threonine 4.5 mg/ml Solvent: Water for injections	15/06/2011	Shire Services BVBA, Belgium

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							(pH= 6.6-7.4)		
Coagadex (1,3)	Human coagulation factor X	Coagulation factor	100 IU/ml (250 or 500 Iu/vial)	Factor X Deficiency	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Citric acid Sodium hydroxide Disodium phosphate dihydrate Sodium chloride Sucrose Solvent: Water for injections	16/03/2016	Bio Products Laboratory Ltd., United Kingdom
Cosentyx (1,2,3)	Secukinumab	Antibody (IgG1k)	150 mg/ml (150 mg/vial)	Ankylosing spondylitis, Psoriatic arthritis, Psoriasis	Powder for solution for injection (single dose)	Subcutaneous use	EMA Sucrose 270 mM Histidine/ Histidine hydrochloride monohydrate 30 mM Polysorbate 80 FDA Sucrose 92.43 mg/ml Histidine/ Histidine hydrochloride monohydrate 4.656 mg/ml Polysorbate 80 0.6 mg/ml (pH= 5.8)	15/01/2015	Novartis Europharm Ltd., United Kingdom
Elocta (Eloctate, FDA) (1,3)	Efmoroctocog alfa	Coagulation factor (antihaemophylic)	83, 167, 250, 333, 500, 667, 1000 IU/ml (250,500,750, 1000,1500,2000,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose Sodium chloride Histidine Calcium chloride dihydrate Polysorbate 20 Sodium hydroxide Hydrochloric acid Solvent: Water for injections	19/11/2015	Swedish Orphan Biovitrum AB (publ), Sweden
Empliciti (1,3)	Elotuzumab	Antibody (IgG1)	25 mg/ml (300,400 mg/vial)	Multiple myeloma	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 42.5 mg/ml Sodium citrate 1.38 mg/ml Citric acid monohydrate 0.20 mg/ml Polysorbate 80 0.28 mg/ml	11/05/2016	Bristol-Myers Squibb Pharma EEIG, United Kingdom
Enbrel (1,3)	Etanercept	Fusion protein	10 or 25 mg/ml (10 mg/ml for paediatric use) (10 or 25 mg/vial)	Ankylosing spondylitis, Rheumatoid arthritis, Psoriatic arthritis, Psoriasis, Juvenile Rheumatoid arthritis	Powder and solvent for solution for injection (multiple dose)	Subcutaneous use	25 mg/ml Powder: Mannitol 40 mg/ml Sucrose 10 mg/ml Tris 1.2 mg/ml Solvent: Water for injections (pH 6.3 ± 0.2) Benzyl alcohol 9 mg/ml	03/02/2000	Pfizer Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Entyvio (1,2,3)	Vedolizumab	Antibody (IgG1)	60 mg/ml (300 mg/vial)	Ulcerative colitis, Crohn disease	Powder for concentrate for solution for infusion (single dose)	Intravenous use	EMA Histidine/Histidine hydrochloride monohydrate 50 mM Arginine hydrochloride 125 mM Sucrose 100 mg/ml Polysorbate 80 0.6 mg/ml FDA Histidine 4.6 mg/ml Histidine hydrochloride monohydrate 4.28 mg/ml Arginine hydrochloride 26.34 mg/ml; Sucrose 100 mg/ml Polysorbate 80 0.6 mg/ml (pH=6.3)	22/05/2014	Takeda Pharma A/S, Denmark
Eperzan (Tanzeum, FDA) (1)	Albiglutide	Hormone/Agonist/Analog	60 or 100 mg/ml (30 or 50 mg/vial)	Diabetes mellitus, type 2	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Sodium dihydrogen phosphate monohydrate/ Disodium phosphate anhydrous (Sodium phosphate) 10 mM Trehalose dihydrate 117 mM Mannitol 153 mM Polysorbate 80 0.1 mg/ml Solvent: Water for injections	21/03/2014	GlaxoSmithKline Trading Services Ltd., Ireland
Extavia (1,3)	Intereferon beta-1b	Cytokine (interferon)	250 µg/ml (300 µg/vial)	Multiple sclerosis	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Human albumin 12.5 mg/ml Mannitol 12.5 mg/ml Solvent: Sodium chloride 5.4 mg/ml Water for injection	20/05/2008	Novartis Europharm Ltd., United Kingdom
Fabrazyme (1,3)	Agalsidase beta	Enzyme	5 mg/ml (5 or 35 mg/vial)	Fabry disease	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Mannitol 30 mg/ml Sodium phosphate monobasic monohydrate 2.73 mg/ml Sodium phosphate dibasic heptahydrate 8 mg/ml	03/08/2001	Genzyme Europe B.V., The Netherlands
Fasturtec (1,2)	Rasburicase	Enzyme	1.5 mg/ml (1.5 mg/vial)	Hyperuricemia	Powder and solvent for concentrate for solution for infusion (single dose)	Intravenous use	Powder: Alanine 15.9 mg/ml Mannitol 10.6 mg/ml Disodium phosphate dodecahydrate Disodium phosphate dihydrate 12.6-14.3 mg/ml Sodium dihydrogen phosphate dehydrate 0.06 mg/ml (Sodium phosphate 40 mM) Solvent:	23/02/2001	Sanofi-Aventis groupe, France

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Poloxamer 188 1 mg/ml Water for injection (pH=8)		
Firmagon (1,3)	Degarelix	Hormone/Agonist/Analog (GnRh antagonist)	20 or 40 mg/ml (80 or 120 mg/vial)	Prostatic neoplasms	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Mannitol 50 mg/ml Solvent: Water for injections	17/02/2009	Ferring Pharmaceuticals A/S, Denmark
Flixabi (Renflexis, FDA) (1,3)	Infliximab	Antibody (IgG1)	10 mg/ml (100 mg/vial)	Ankylosing spondylitis, Rheumatoid arthritis, Ulcerative colitis, Psoriatic arthritis, Crohn disease, Psoriasis	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Polysorbate 80 0.05 mg/ml Monobasic sodium phosphate monohydrate 0.56 mg/ml Dibasic sodium phosphate heptahydrate 0.26 mg/ml (pH=6.2)	26/05/2016	Samsung Bioepis Ltd., United Kingdom
Fuzeon (1,3)	Enfuvirtide	HIV fusion inhibitor	90 mg/ml (108 mg/vial)	HIV Infections	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Sodium carbonate 2.39 mg/ml Mannitol 22.55 mg/ml Sodium hydroxide Hydrochloric acid Solvent: Water for injections (pH=9)	27/05/2003	Roche Registration Ltd., United Kingdom
GONAL-f (Gonal-f and Gonal-f RFF, FDA) (1,3)	Follitropin alfa	Hormone/Agonist/Analog	75 or 600 IU/ml (75,300,450,900,1050 IU/vial)	Female infertility, Assisted reproductive techniques, Anovulation, Hypogonadism	Powder and solvent for solution for injection (single and multiple dose)	Subcutaneous use	<u>75 IU/ml (single dose)</u> Powder: Sucrose 30 mg/ml Sodium dihydrogen phosphate monohydrate 0.45 mg/ml Disodium phosphate dihydrate 1.11 mg/ml Methionine 0.1 mg/ml Polysorbate 20 0.05 mg/ml Phosphoric acid concentrated Sodium hydroxide Solvent: Water for injections <u>600 IU/ml (multiple dose)</u> Powder: Sucrose 30 mg/ml Sodium dihydrogen phosphate monohydrate 0.45 mg/ml Disodium phosphate dihydrate 1.11 mg/ml	20/10/1995	Merck Serono Europe Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Methionine 0.1 mg/ml Polysorbate 20 0.05 mg/ml Phosphoric acid concentrated Sodium hydroxide Solvent: Water for injections Benzyl alcohol 9 mg/ml		
Helixate NexGen (Helixate FS, FDA) (1,2,3)	Octocog alfa	Coagulation factor (antihaemophylic)	100, 200, 400, 600 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	EMA Powder: Glycine 23.2 mg/ml Sodium chloride 1.76 mg/ml Calcium chloride 0.28 mg/ml Histidine 3.2 mg/ml Polysorbate 80 Sucrose 11.2 mg/ml Solvent: Water for injections FDA Powder: Glycine 21-25 mg/ml Sodium chloride 27-40 mEq/L Calcium chloride 2-3 mM Histidine 18-23 mM Polysorbate 80 0.064-0.096 mg/ml Sucrose 9-13 mg/ml Solvent: Water for injections	04/08/2000	Bayer AG, Germany
Herceptin (another strength, FDA) (1,3)	Trastuzumab	Antibody (IgG1)	21 mg/ml (150 mg/vial)	Stomach neoplasms, Breast neoplasms	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Histidine hydrochloride monohydrate 0.48 mg/ml Histidine 0.31 mg/ml Trehalose dihydrate 19.05 mg/ml Polysorbate 20 0.08 mg/ml (pH=6)	28/08/2000	Roche Registration Ltd., United Kingdom
Herzuma (same composition of Herceptin except for trehalose concentration, FDA) (1,2,3)	Trastuzumab	Antibody (IgG1)	21 mg/ml (150 mg/vial)	Stomach neoplasms, Breast neoplasms	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Histidine hydrochloride 0.48 mg/ml Histidine 0.31 mg/ml Trehalose dihydrate Polysorbate 20 0.08 mg/ml (pH=6)	09/02/2018	Celltrion Healthcare Hungary Kft.

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Iblias (same composition of Kogenate FS, FDA) (1,2,3)	Octocog alfa	Coagulation factor (antihaemopylic)	100, 200, 400, 600 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Glycine 23.2 mg/ml Sodium chloride 1.76 mg/ml Calcium chloride 0.28 mg/ml Histidine 3.2 mg/ml Polysorbate 80 Sucrose 11.2 mg/ml Solvent: Water for injections	18/02/2016	Bayer AG, Germany
Idelvion (1,3)	Albutrepenonacog- alfa	Coagulation factor	100, 200, 400 IU/ml (250,500,1000,2000 IU/vial)	Haemophilia B	Powder and solvent for solution for injection (single dose)	Intravenous use	<u>100 IU/ml</u> Powder: Tri-sodium citrate dihydrate 6.5 mg/ml Polysorbate 80 0.06 mg/ml Mannitol 18 mg/ml Sucrose 7 mg/ml Hydrochloric acid Solvent: Water for injections	11/05/2016	CSL Behring GmbH, Germany
							<u>200 IU/ml</u> Powder: Tri-sodium citrate dihydrate 6.5 mg/ml Polysorbate 80 0.12 mg/ml Mannitol 29 mg/ml Sucrose 12 mg/ml Hydrochloric acid Solvent: Water for injections		
							<u>400 IU/ml</u> Powder: Tri-sodium citrate dihydrate 6.5 mg/ml Polysorbate 80 0.24 mg/ml Mannitol 29 mg/ml Sucrose 12 mg/ml Hydrochloric acid Solvent: Water for injections		
Ilaris (1,3)	Canakinumab	Antibody (IgG1k)	150 mg/ml (150 mg/vial)	Cryopyrin-associated periodic syndromes, Juvenile rheumatoid arthritis, Gouty arthritis	Powder for solution for injection (single dose)	Subcutaneous use	Sucrose 92.4 mg/ml Histidine 2.8 mg/ml Histidine hydrochloride monohydrate 1.7 mg/ml Polysorbate 80 0.6 mg/ml	23/10/2009	Novartis Europharm Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Inflectra (1,3)	Infliximab	Antibody (IgG1)	10 mg/ml (100 mg/vial)	Ankylosing spondylitis, Rheumatoid Arthritis, Ulcerative Colitis, Psoriatic Arthritis, Crohn disease, Psoriasis	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Polysorbate 80 0.05 mg/ml Sodium dihydrogen phosphate monohydrate 0.22 mg/ml Disodium phosphate dihydrate 0.61 mg/ml (pH=7.2)	10/09/2013	Hospira Ltd., United Kingdom
Kadcyla (1,3)	Trastuzumab emtansine	Antibody-drug conjugate (ADC) (IgG1)	20 mg/ml (100 or 160 mg/vial)	Breast neoplasms	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Succinic acid/ Sodium hydroxide (Sodium succinate) 10 mM Sucrose 60 mg/ml Polysorbate 20 0.2 mg/ml (pH=5)	15/11/2013	Roche Registration GmbH, Germany
Kanjinti (same composition of Herceptin, FDA) (1,2,3)	Trastuzumab	Antibody (IgG1)	21 mg/ml (150/420 mg/vial)	Stomach Neoplasms Breast Neoplasms	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Histidine 0.31 mg/ml Histidine monohydrochloride 0.48 mg/ml Trehalose dihydrate 19.05 mg/ml Polysorbate 20 0.08 mg/ml	16/05/2018	Amgen Europe B.V., Breda
Keytruda (1,3)	Pembrolizumab	Antibody (IgG4k)	25 mg/ml (50 mg/vial)	Non-small-cell lung carcinoma Hodgkin disease, Melanoma	Powder for 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 (pH=5.2-5.8, EMA; pH=5.5,FDA)	17/07/2015	Merck Sharp and Dohme Ltd.
Kogenate Bayer (Kogenate FS, FDA) (1,2,3)	Octocog alfa	Coagulation factor (antihaemophylic)	100, 200, 400, 600 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	<u>EMA</u> Powder: Glycine 23.2 mg/ml Sodium chloride 1.76 mg/ml Calcium chloride 0.28 mg/ml Histidine 3.2 mg/ml Polysorbate 80 Sucrose 11.2 mg/ml Solvent: Water for injections <u>FDA 250,500,1000 IU/ml</u> Powder: Glycine 21-25 mg/ml Sodium 27-36 mEq/L Calcium 2-3 mM Chloride 32-40 mEq/L Polysorbate 80 0.064-0.096 mg/ml Sucrose 9-12 mg/ml Solvent: Water for injections	04/08/2000	Bayer AG, Germany

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							FDA 2000,3000 IU/ml Powder: Glycine 20-24 mg/ml Sodium 26-34 mEq/L Calcium 1.9-2.9 mM Chloride 31-38 mEq/L Polysorbate 80 0.064-0.096 mg/ml Sucrose 9-13 mg/ml Solvent: Water for injections		
Kovaltry (1,3)	Octocog alfa	Coagulation factor (antyhaemophilic)	100, 200, 400, 600 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose 10 mg/ml Histidine 20 mM Glycine 22 mg/ml Sodium chloride 30 mM Calcium chloride 2.5 mM Polysorbate 80 80 ppm Solvent: Water for injections (pH=6.6-7)	18/02/2016	Bayer AG, Germany
Kyprolis (1,3)	Carflizomib	Enzyme inhibitor	2 mg/ml (10,30,60 mg/vial)	Multiple Myeloma	Powder for solution for infusion (single dose)	Intravenous use	Betadex sulfobutyl ether sodium 100 mg/ml Anhydrous citric acid 1.93 mg/ml Sodium hydroxide pH= 3.5	19/11/2015	Amgen Europe B.V, The Netherlands
Lamzede (1)	Velmanase alfa	Enzyme	2 mg/ml (10 mg/vial)	alpha-Mannosidosis	Powder for solution for infusion (single dose)	Intravenous use	Disodium phosphate dihydrate Sodium dihydrogen phosphate dihydrate Mannitol Glycine (pH=7.5±0.5)	23/03/2018	Chiesi Farmaceutici S.p.A.
Lifmior (same composition of Enbrel, FDA) (1,2,3)	Etanercept	Fusion protein	10 or 25 mg/ml (10 or 25 mg/vial)	Ankylosing spondylitis, Psoriatic arthritis, Psoriasis	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Mannitol 40 mg/ml Sucrose 10 mg/ml Tris 1.2 mg/ml Solvent: Water for injection	13/02/2017	Pfizer Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Luveris (1,3)	Lutropin alfa	Hormone/Agonist/Analog	75 IU/ml (75 IU/vial)	Female Infertility, Ovulation induction	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Sucrose 43.6 mg/ml Disodium phosphate dihydrate 0.76 mg/ml Sodium dihydrogen phosphate monohydrate 0.05 mg/ml Polysorbate 20 0.05 mg/ml Phosphoric acid Sodium hydroxide Methionine 0.09 mg/ml Nitrogen Solvent: Water for injection (pH= 7.5-8.5)	29/11/2000	Merck Serono Europe Ltd., United Kingdom
Mepact (1)	Mifamurtide	Muramylpeptide derivative	0.08 mg/ml (4 mg/vial)	Osteosarcoma	Powder for concentrate for dispersion for infusion (single dose)	Intravenous use	1-Palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine (POPC) 1,2-Dioleoyl-sn-glycero-3-phospho-L-serine monosodium salt (OOPS)	06/03/2009	Takeda France SAS, France
Metalyse (TNKase, FDA) (1,3)	Tenecteplase	Enzyme	5 mg/ml (40 or 50 mg/vial)	Myocardial infarction	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Arginine 52 mg/ml Phosphoric acid 16 mg/ml Polysorbate 20 0.4 mg/ml Solvent: Water for injections	23/02/2001	Boehringer Ingelheim International GmbH, Germany
Mylotarg (1,3)	gemtuzumab ozogamicin	Antibody-drug coniugate (ADC) (IgG4k)	1 mg/ml (5 mg/vial)	Acute Myeloid Leucemia	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Dextran 40 9.1 mg/ml Sucrose 15.5 mg/ml Sodium chloride 5.8 mg/ml Sodium dihydrogen phosphate monohydrate 0.1 mg/ml Disodium hydrogen phosphate anhydrous 0.6 mg/ml	19/04/2018	Pfizer Limited
Myozyme (1,3)	Alglucosidase alfa	Enzyme	5 mg/ml (50 mg/vial)	Glycogen storage disease type II	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Mannitol 20 mg/ml Sodium dihydrogen phosphate monohydrate 2.97 mg/ml Disodium phosphate heptahydrate 0.94 mg/ml Polysorbate 80 0.05 mg/ml	29/03/2006	Genzyme Europe B.V., The Netherlands
Natpar (Natpara, FDA) (1,3)	Parathyroid hormone	Hormone/Agonist/Analog	350, 700, 1050, 1400 µg/ml (25,50,75,100 µg/vial)	Hypoparathyroidism	Powder and solvent for solution for injection (multiple dose)	Subcutaneous use	Powder: Sodium chloride 3.98 mg/ml Mannitol 26.55 mg/ml Citric acid monohydrate 1.12 mg/ml Sodium hydroxide Solvent: Metacresol 3.2 mg/ml	24/04/2017	Shire Pharmaceuticals Ltd.,Ireland

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections		
NeoRecormon (composition reported only for the liquid product) (1)	Epoetin beta	Hormone/Agonist/Analog	5000 IU/ml (50000 IU/vial)	Anemia, Chronic kidney failure, Autologous blood transfusion, Cancer	Powder and solvent for solution for injection (multiple dose)	Intravenous use or subcutaneous use	Powder: Urea Sodium chloride Polysorbate 20 Sodium dihydrogen phosphate Disodium hydrogen phosphate Calcium chloride Glycine Leucine Isoleucine Threonine Glutamic acid Phenylalanine Solvent: Benzyl alcohol Benzalkonium chloride Water for injections	16/07/1997	Roche Registration Ltd., United Kingdom
Nonafact (1,2)	Human coagulation factor IX	Coagulation factor	100 IU/ml (500,1000 IU/vial)	Haemophilia B	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sodium chloride 75 mM Sucrose 151 mM Histidine 15 mM Solvent: Water for injections	03/07/2001	Sanquin Plasma Products B.V., The Netherlands
NovoEight (1,3)	Turoctocog alfa	Coagulation factor (antihaemophylic)	62.5, 125, 250, 375, 500 or 750 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sodium chloride 18 mg/ml Histidine 1.5 mg/ml Sucrose 3 mg/ml Polysorbate 80 0.1 mg/ml Methionine 0.055 mg/ml Calcium chloride dihydrate 0.25 mg/ml Sodium hydroxide Hydrochloric acid Solvent: Sodium chloride 9 mg/ml Water for injections	13/11/2013	Novo Nordisk A/S, Denmark
NovoSeven (FDA product has a different strength and excipient composition) (1,4)	Eptacog alfa (activated)	Coagulation factor (antihaemophylic)	1 mg/ml (1,2,5,8 mg/vial)	Haemophilia B, Thrombasthenia, Factor VII deficiency, Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sodium chloride 2.3 mg/ml Calcium chloride dihydrate 1.5 mg/ml Glycylglycine 1.5 mg/ml Polysorbate 80 0.1 mg/ml Mannitol 25 mg/ml Sucrose 10 mg/ml Methionine 0.5 mg/ml	23/02/1996	Novo Nordisk A/S., Denmark

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Hydrochloric acid Sodium hydroxide Solvent Histidine 1.6 mg/ml Hydrochloric acid Sodium hydroxide Water for injections (pH= 6)		
NovoThirteen (Tretten, FDA) (1,4)	Catridecacog	Coagulation factor (antyhaemophilic)	833 IU/ml (2500 IU/vial)	Inherited blood coagulation disorders	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sodium chloride 2.72 mg/ml Sucrose 54.38 mg/ml Polysorbate 20 0.094 mg/ml Histidine 2.9 mg/ml Hydrochloric acid Sodium hydroxide Solvent: Water for injections	03/09/2012	Novo Nordisk A/S, Denmark
Nplate (1,3)	Romiplostim	Fusion protein	500 µg/ml (125,250,500 µg/vial)	Idiopathic thrombocytopenic purpura	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Mannitol 40 mg/ml Sucrose 20 mg/ml Histidine 1.52 mg/ml Hydrochloric acid Polysorbate 20 0.04 mg/ml (pH=5)	04/02/2009	Amgen Europe B.V., The Netherlands
Nucala (1,3)	Mepolizumab	Antibody (IgG1k)	100 mg/ml (100 mg/vial)	Asthma	Powder for solution for injection (single dose)	Subcutaneous use	Sucrose 160 mg/ml Sodium phosphate dibasic heptahydrate 7.14 mg/ml Polysorbate 80 0.67 mg/ml (pH=7)	02/12/2015	GlaxoSmithKline Trading Services Ltd., Ireland
Nulojix (1,3)	Belatacept	Fusion protein	25 mg/ml (250 mg/vial)	Kidney transplantation, Graft rejection	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Sodium dihydrogen phosphate monohydrate 3.45 mg/ml Sodium chloride 0.58 mg/ml Sodium hydroxide Hydrochloric acid (pH=7.2-7.8)	17/06/2011	Bristol-Myers Squibb Pharma EEIG, United Kingdom
Nuwiq (1,3)	Simoctocog alfa	Coagulation factor (anti haemophylic)	100, 200, 400, 800, 1000, 1200,1600 IU/ml (250,500,1000,2000,3000, 4000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose 5.4 mg/ml Sodium chloride 18 mg/ml Calcium chloride dihydrate 0.3 mg/ml Arginine hydrochloride 5.4 mg/ml Sodium citrate dihydrate 1.2 mg/ml Poloxamer 188 1.2 mg/ml Solvent: Water for injections	22/07/2014	Octapharma AB, Sweden

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Obizur (1,3)	Susoctocog-alpha	Coagulation factor (antihaemophylic)	500 IU/ml (500 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Polysorbate 80 0.05 mg/ml Sodium chloride 8.8 mg/ml Calcium chloride dihydrate 0.15 mg/ml Sucrose 1.9 mg/ml Tris base 0.04 mg/ml Tris HCl 0.73 mg/ml Tri-sodium citrate dihydrate 1.47 mg/ml Solvent: Sterilised water for injections	11/11/2015	Baxalta Innovations GmbH., Austria
Omnitrope (1,3)	Somatropin	Hormone/Agonist/Analog	1.3 or 5 mg/ml (5.8 mg/vial)	Prader-Willi syndrome, Pituitary dwarfism, Turner syndrome	Powder and solvent for solution for injection (single and multiple dose)	Subcutaneous use	<u>1.3 mg/ml (single dose)</u> Powder: Glycine 24.2 mg/ml Disodium hydrogen phosphate heptahydrate 1.83 mg/ml Sodium dihydrogen phosphate dihydrate 0.49 mg/ml Solvent: Water for injections <u>5 mg/ml (multiple dose)</u> Powder: Glycine 24.2 mg/ml Disodium hydrogen phosphate heptahydrate 1.83 mg/ml Sodium dihydrogen phosphate dihydrate 0.49 mg/ml Solvent: Water for injections Benzyl alcohol 14.9 mg/ml	12/04/2006	Sandoz GmbH, Austria
Ontruzant (same composition of Herceptin, FDA) (1,2,3)	Trastuzumab	Antibody (IgG1)	21 mg/ml (150 mg/vial)	Stomach neoplasms, Breast neoplasms	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Histidine hydrochloride monohydrate 0.48 mg/ml Histidine 0.31 mg/ml α,α-Trehalose dihydrate 19.05 mg/ml Polysorbate 20 0.08 mg/ml (pH=6)	15/11/2017	Samsung Bioepis Ltd. (SBUK), United Kingdom
Orencia (1,3)	Abatacept	Fusion protein	25 mg/ml (250 mg/vial)	Rheumatoid arthritis, Juvenile rheumatoid arthritis	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Maltose 50 mg/ml Sodium dihydrogen phosphate monohydrate 1.72 mg/ml Sodium chloride 1.46 mg/ml (pH=7.2-7.8)	21/05/2007	Bristol-Myers Squibb Pharma EEIG, United Kingdom
PegIntron (1,3)	Peginterferon alfa-2b	Cytokine (interferon)	100, 160, 200, 240, 300 µg/ml	Chronic Hepatitis C	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Disodium phosphate anhydrous 1.59 mg/ml Sodium dihydrogen phosphate dihydrate 1.59 mg/ml	25/05/2000	Merck Sharp & Dohme Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
			(50,80,100,120,150 µg/vial)				Sucrose 84.57 mg/ml Polysorbate 80 0.1 mg/ml Solvent: Water for injections		
Pergoveris (1,4)	Follitropin alfa/lutropin alfa	Hormone/Agonist/Analog	150 IU/ml (follitropin alfa)/75 IU/ml (lutropin alfa) (150 IU (follitropin alfa) and 75 IU (lutropin alfa)/vial)	Female infertility	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Sucrose 30 mg/ml Polysorbate 20 0.05 mg/ml Methionine 0.1 mg/ml Disodium phosphate dihydrate 1.11 mg/ml Sodium dihydrogen phosphate monohydrate 0.45 mg/ml Phosphoric acid concentrated Sodium hydroxide Solvent: Water for injections (pH=6.5-7.5)	25/06/2007	Merck Serono Europe Ltd., United Kingdom
Rapilysin (Retavase, FDA) (1,3)	Reteplase	Thrombolitic factor	1 IU/ml (10 IU/vial)	Myocardial infarction	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Tranexamic acid 0.832 mg/ml Di-potassium-hydrogen phosphate 3.624 mg/ml Phosphoric acid 5.127 mg/ml Sucrose 36.4 mg/ml Polysorbate 80 0.52 mg/ml Solvent: Water for injections	29/08/1996	Actavis Group PTC ehf, Iceland
ReFacto AF (Refacto, FDA) (1,3)	Moroctocog alfa	Coagulation factor (antyhaemophylic)	62.5, 125, 250, 500 or 750 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose Calcium chloride dihydrate Histidine Polysorbate 80 Sodium chloride Solvent: Sodium chloride Water for injections	13/04/1999	Pfizer Ltd., United Kingdom
Refixia (1)	Nonacog beta pegol	Coagulation factor	125, 250, 500 IU/ml (500,1000,2000 IU/vial)	Haemophilia B	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sodium chloride Histidine Sucrose Polysorbate 80 Mannitol Sodium hydroxide Hydrochloric acid Solvent: Histidine	02/06/2017	Novo Nordisk A/S, Denmark

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections Sodium hydroxide Hydrochloric acid		
Remicade (1,3)	Infliximab	Antibody (IgG1)	10 mg/ml (100 mg/vial)	Ankylosing spondylitis, Rheumatoid arthritis, Ulcerative colitis, Psoriatic arthritis, Crohn disease, Psoriasis	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Polysorbate 80 0.05 mg/ml Monobasic sodium phosphate 0.22 mg/ml Dibasic sodium phosphate 0.61 mg/ml (pH=7.2)	13/08/1999	Janssen Biologics B.V., The Netherlands
Remsima (same composition of Remicade) (1,2,3)	Infliximab	Antibody (IgG1)	10 mg/ml (100 mg/vial)	Ankylosing spondylitis, Rheumatoid arthritis, Ulcerative colitis, Psoriatic arthritis, Crohn disease, Psoriasis	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Polysorbate 80 0.05 mg/ml Sodium dihydrogen phosphate monohydrate 0.22 mg/ml Disodium phosphate dihydrate 0.61 mg/ml (pH=7.2)	10/09/2013	Celltrion Healthcare Hungary Kft., Hungary
Respreeza (Zemaira, FDA) (1,2,3)	Human alpha1-proteinase inhibitor	Enzyme inhibitor	50 mg/ml (1000 mg/vial)	Inborn genetic diseases, Lung diseases	Powder and solvent for solution for infusion (single dose)	Intravenous use	Powder: Sodium 73-89 mM Chloride 33-42 mM Sodium dihydrogen phosphate monohydrate 15-20 mM Mannitol 121-168 mM Solvent: Water for injection (pH=7)	20/08/2015	CSL Behring GmbH., Germany
Revestive (1)	Teduglutide	Hormone/Agonist/Analog	2.5 mg/ml (1.25 mg/vial)	Malabsorption syndromes	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Histidine Mannitol Sodium phosphate monohydrate Disodium phosphate heptahydrate Solvent: Water for injection	30/08/2012	Shire Pharmaceuticals Ltd., Ireland
Revestive (Gattex, FDA) (1,3)	Teduglutide	Hormone/Agonist/Analog	10 mg/ml (5 mg/vial)	Malabsorption syndromes	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Histidine 7.76 mg/ml Mannitol 30 mg/ml Sodium phosphate monohydrate 1.288 mg/ml Disodium phosphate heptahydrate 6.868 mg/ml Sodium hydroxide Hydrochloric acid Solvent: Water for injection	30/08/2012	Shire Pharmaceuticals Ltd., Ireland

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
Rixubis (1,2)	Nonacog gamma	Coagulation factor (antihaemophylic)	50, 100, 200, 400 or 600 IU/ml (250,500,1000,2000,3000 IU/vial)	Haemophilia B	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose 35 mM Mannitol 110 mM Sodium chloride 60 mM Calcium chloride 4 mM Histidine 20 mM Polysorbate 80 0.05 mg/ml Solvent: Sterilised water for injection	19/12/2014	Baxalta Innovations GmbH, Austria
Ruconest (1,3)	Conestat alfa	Enzyme inhibitor	150 IU/ml (2100 IU/vial)	Hereditary Angioedemas	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose 66.93 mg/ml Sodium citrate 5.95 mg/ml Citric acid 0.071 mg/ml Solvent: Water for injections (pH=6.8)	28/10/2010	Pharming Group N.V., The Netherlands
Simulect (1,3)	Basiliximab	Antibody (IgG1k)	4 mg/ml (10 or 20 mg/vial)	Kidney transplantation, Graft rejection	Powder and solvent for solution for injection or infusion (single dose)	Intravenous use	Powder: Potassium dihydrogen phosphate 1.44 mg/ml Disodium phosphate anhydrous 0.20 mg/ml Sodium chloride 0.32 mg/ml Sucrose 4 mg/ml Mannitol 16 mg/ml Glycine 8 mg/ml Solvent: Water for injections (pH=4)	09/10/1998	Novartis Europharm Ltd., United Kingdom
Somavert (1,3)	Pegvisomant	Hormone antagonist	10, 15, 20, 25, 30 mg/ml (10,15,20,25, 30 mg/vial)	Acromegaly	Powder and solvent for solution for injection (single dose)	Subcutaneous use	<u>10,15,20 mg/ml</u> Powder: Glycine 1.36 mg/ml Mannitol 36 mg/ml Disodium phosphate anhydrous 1.04 mg/ml Sodium dihydrogen phosphate monohydrate 0.36 mg/ml Solvent: Water for injections <u>25 mg/ml</u> Powder: Glycine 1.7 mg/ml Mannitol 45 mg/ml Disodium phosphate anhydrous 1.3 mg/ml	13/11/2002	Pfizer Ltd., United Kingdom

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Sodium dihydrogen phosphate monohydrate 0.45 mg/ml Solvent: Water for injections <u>30 mg/ml</u> Powder: Glycine 2.04 mg/ml Mannitol 54 mg/ml Disodium phosphate anhydrous 1.56 mg/ml Sodium dihydrogen phosphate monohydrate 0.54 mg/ml Solvent: Water for injections		
Spectrila (1)	Asparaginase	Enzyme	2500 IU/ml (10000 IU/vial)	Precursor cell, Lymphoblastic leukemia-lymphoma	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Sucrose	14/01/2016	Medac GmbH Germany
Sylvant (1,3)	Siltuximab	Antibody (IgG1k)	20 mg/ml (100,400 mg/vial)	Giant lymph node hyperplasia	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Histidine/ Histidine hydrochloride monohydrate 0.74 mg/ml Polysorbate 80 0.16 mg/ml Sucrose 33.8 mg/ml (pH=5.2)	22/05/2014	Janssen-Cilag International NV, Belgium
Synagis (FDA product is in the liquid state and it has different excipient composition) (1,2)	Palivizumab	Antibody (IgG1k)	100 mg/ml (50,100 mg/vial)	Respiratory syncytial virus infections	Powder and solvent for solution for injection (single dose)	Intramuscular use	Powder: Histidine 7.3 mg/ml Glycine 0.2 mg/ml Mannitol 56.3 mg/ml Solvent: Water for injections	13/08/1999	AbbVie Ltd., United Kingdom
Thyrogen (1,3)	Thyrotropin alfa	Hormone/Agonist/Analog	0.9 mg/ml (0.9 mg/vial)	Thyroid neoplasms	Powder for solution for injection (single dose)	Intramuscular use	Mannitol 30 mg/ml Sodium phosphate monobasic monohydrate/Sodium phosphate dibasic heptahydrate 4.25 mg/ml Sodium chloride 2 mg/ml	09/03/2000	Genzyme Europe B.V., The Netherlands
Vihuma (same composition of Nuwiq, FDA) (1,2,3)	Simoctocog alfa	Coagulation factor	100, 200, 400, 800 IU/ml (250,500,1000,2000 IU/vial)	Haemophilia A	Powder and solvent for solution for injection (single dose)	Intravenous use	Powder: Sucrose 5.4 mg/ml Sodium chloride 18 mg/ml Calcium chloride dihydrate 0.3 mg/ml Arginine hydrochloride 5.4 mg/ml Sodium citrate dihydrate 1.2 mg/ml Poloxamer 188 1.2 mg/ml Solvent:	13/02/2017	Octapharma AB, Sweden

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
							Water for injections		
ViraferonPeg (1)	Peginterferon alfa-2b	Cytokine (interferon)	100, 160, 200, 240, 300 µg/ml (50,80,100,120,150 µg/vial)	Chronic hepatitis C	Powder and solvent for solution for injection (single dose)	Subcutaneous use	Powder: Disodium phosphate anhydrous Sodium dihydrogen phosphate dehydrate Sucrose 80 mg/ml Polysorbate 80 Solvent: Water for injections	29/05/2000	Merck Sharp & Dohme Ltd., United Kingdom
Voncento (1)	Human coagulation factor VIII (FVIII)/Human von Willebrand factor (VWF)	Coagulation factor	50 IU/ml (FVIII)/120 IU/ml (VWF) or 100 IU/ml (FVIII)/240 IU/ml (VWF) (250 IU (FVIII)-600IU (VWF)/vial; 500 IU (FVIII)-1200 IU (VWF)/vial; 1000 IU (FVIII)-2400 IU (VWF)/vial)	von Willebrand diseases, Haemophilia A	Powder and solvent for solution for injection/infusion (single dose)	Intravenous use	Powder: Calcium chloride Human albumin Sodium chloride Sodium citrate Sucrose Tris Solvent: Water for injections	12/08/2013	CSL Behring GmbH, Germany
Vpriv (1,3)	Velaglucerase alfa	Enzyme	100 IU/ml (400 IU/vial)	Gaucher disease	Powder for solution for infusion (single dose)	Intravenous use	Sucrose 50 mg/ml Sodium citrate dihydrate 12.94 mg/ml Citric acid monohydrate 1.26 mg/ml Polysorbate 20 0.11 mg/ml	26/08/2010	Shire Pharmaceuticals Ltd., Ireland
Xolair (1,3)	Omalizumab	Antibody (IgG1k)	125 mg/ml (75,150 mg/vial)	Urticaria, Asthma	Powder and solvent for solution for injection (single dose)	Subucutaneous use	Powder: Sucrose 104 mg/ml Histidine 1.3 mg/ml Histidine hydrochloride monohydrate 2 mg/ml Polysorbate 20 0.36 mg/ml Solvent: Water for injections (pH= 5.5-6.5)	25/10/2005	Novartis Europharm Ltd., United Kingdom
Zessly (1)	Infliximab	Antibody (IgG1)	10 mg/ml (100 mg/vial)	Ankylosing Spondylitis, Rheumatoid Arthritis, Ulcerative	Powder for concentrate for solution for infusion (single dose)	Intravenous use	Disodium succinate hexahydrate Succinic acid Sucrose Polysorbate 80	18/05/2018	Sandoz GmbH

Commercial name	API	Type of protein	API quantitative composition	Therapeutic Area	Dosage form	Route of administration	Excipient composition	Date of first approval (European Union)	Marketing authorisation holder (European Union)
				Colitis, Psoriatic Arthritis, Crohn Disease, Psoriasis					

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 information 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'

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