

EU CTD Dossier List

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
1	Amlodipine + Valsartan Tablets	5+80 / 5+160 / 10+160 mg	Exforge®	Available	Completed	Cardiology
2	Amlodipine + Valsartan + HCTZ Tablets	5+160+12.5 / 5+160+25 / 10+160+12.5 / 10+160+25 / 10+320+25 mg	Exforge Hct®	Available	Completed	Cardiology
3	Apixaban Tablets	2.5 / 5 mg	Eliquis®	Available	Completed	Cardiology
4	Apremilast Tablets	30 mg	Otezla®	Available	Completed	Anti-psoriatic arthritis
5	Aripiprazole Tablets	5 / 10 / 15 / 20mg/ 30 mg	Abilify®	Available	Completed	Central Nervous System
6	Atomoxetine Capsules	10 / 18 / 25 / 40 / 60 / 80 / 100 mg	Strattera®	Available	Completed	ADHD
7	Canagliflozin Tablets	100 / 300 mg	Neomercazole®	Available	Completed	Diabetology
8	Carbimazole Tablets	5 / 10 / 15 / 20 mg		Available		Anti hyperthyroidism
9	Celecoxib Capsules	100 / 200 mg	Celebrex®	Available	Completed	Pain Management
10	Cinacalcet Tablets	30 / 60 / 90 mg	Mimpara®	Available	Completed	Endocrinology
11	Clopidogrel Tablets	75 mg	Plavix®	Available	Completed	Cardiology
12	Colchicine Tablets	0.5 / 1 mg	Colchicine, Wockhardt	Available	Completed	Anti-gout
13	Dapagliflozin Tablets	5 / 10 mg	Forxiga®	Available	Completed	Diabetology
14	Dapagliflozin + Metformin Tablets	5+850 / 5+1000 mg	Xigduo®	Available	Ongoing	Diabetology
15	Dapsone Tablets	25 / 50 / 100 mg	Dapsone (50 Mg) Accord Barnstaple, Dapsone (100 Mg) Actavis Barnstaple From Uk	Available	Completed	Anti-Infective
16	Dimethyl Fumarate GR Capsules	120 / 240 mg	Tecfidera®	Available	Completed	Multiple Sclerosis
17	Dolutegravir Tablets	50 mg	Tivicay®	Available	Ongoing	Anti-Retroviral
18	Donepezil OD Tablets	5 / 10 mg	Aricept Evess®	Available	Completed	Central Nervous System
19	Donepezil Tablets	5 / 10 mg	Aricept®	Available	Completed	Central Nervous System

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
20	Dutasteride Capsules	0.5 mg	Avodart®	Available	Ongoing	Urology
21	Empagliflozin Tablets	10 / 25 mg	Jardiance®	Available	Ongoing	Diabetology
22	Empagliflozin + Metformin Tablets	5+850 / 5+1000 / 12.5+850 / 12.5+1000 mg	Synjardy®	Available	Ongoing	Diabetology
23	Escitalopram Tablets	5 / 10 / 20 mg	Cipralex®	Available	Completed	Central Nervous System
24	Febuxostat Tablets	80 / 120 mg	Adenuric®	Available	Completed	Anti-gout
25	Hydrocortisone sodium succinate	100 mg/vial	Solu Cortef	Available	Ongoing	Steroid
26	Irbesartan Tablets	75 / 150 / 300 mg	Aprovel®	Available	Completed	Cardiology
27	Irbesartan + HCTZ Tablets	150+12.5 / 300+12.5 / 300+25 mg	Coaprovel®	Available	Completed	Cardiology
28	Isoniazid Tablets	100 mg	Isoniazid, Rph Pharmaceuticals	Available	Completed	Anti-Tuberculosis
29	Lacosamide Tablets	50 / 100 / 150 / 200 mg	Vimpat®	Available	Completed	Central Nervous System
30	Lamivudine Tablets	100 / 150 / 300 mg	Epivir®-300/150, Zeffix®-100	Available	Completed	Anti-Retroviral
31	Lamivudine + Abacavir Tablets	300+600 mg	Kivexa®	Available	Completed	Anti-Retroviral
32	Lenalidomide capsule	2.5, 5, 7.5, 10, 15, 20, 25 mg	Revlimid®	Available		Oncology
33	Levodopa + Carbidopa + Entacapone Tablets	50+12.5+200 / 75+18.75+200 / 100+25+200 / 125+31.25+200 / 150+37.5+200 / 200+50+200 / 175+43.75+200 mg	Stalevo®	Available	Completed	Central Nervous System
34	Levodropropizine Syrup	60 mg / 10 ml	Levopront, Dompe Farmaceutici	Available	Completed	Respiratory
35	Levofloxacin Tablets	250 / 500 mg	Tavanic®	Available	Completed	Anti-Infective
36	Levothyroxine tablets	25 / 50 / 75 / 88 / 100 / 112 / 125 / 137 / 150 / 175 / 200 mcg	Euthyrox®	Available	Ongoing	Endocrinology
37	Linagliptin Tablets	5 mg	Trajenta®	Available	Completed	Diabetology
38	Linagliptin + Metformin Tablets	2.5+850 / 2.5+1000 mg	Jentadueto®	Available	Ongoing	Diabetology
39	Linezolid Tablets	600 mg	Zyvox®	Available	Ongoing	Anti-bacterial
40	Memantine HCL Tablets	10 / 20 mg	Ebixa®	Available	Completed	Central Nervous System

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
41	Memantine Oral solution	10 mg/ml (5 mg/pump)	Ebixa [®]	Available	Completed	Central Nervous System
42	Moxifloxacin Tablets	400 mg	Avelox [®]	Available	Completed	Anti-Infective
43	Nebivolol Tablets	1.25 / 2.5 / 5 / 10 mg	Nebilet [®]	Available	Completed	Cardiology
44	Nintedanib Capsules	100 / 150 mg	Ofev [®]	Available	Ongoing	Respiratory
45	Nortriptyline Tablets	10 / 25 / 50 mg	Allegron, King Pharma, Uk	Available	Completed	Central Nervous System
46	Olmesartan Tablets	10 / 20 / 40 mg	Olmetec [®]	Available	Completed	Cardiology
47	Olmesartan + Amlodipine Tablets	20+5 / 40+5 / 40+10 mg	Sevikar [®]	Available	Completed	Cardiology
48	Olmesartan + Amlodipine + HCTZ Tablets	20+5+12.5 / 40+5+12.5 / 40+5+25 / 40+10+12.5 / 40+10+25 mg	Sevikar Hct [®]	Available	Completed	Cardiology
49	Olmesartan + HCTZ Tablets	20+12.5 / 20+25 / 40+12.5 / 40+25 mg	Olmetec Hct [®]	Available	Completed	Cardiology
50	Pantoprazole Gastro Resistant Tablets	20 / 40 mg	Protium [®]	Available	Completed	Gastroenterology
51	Pirfenidone Capsules	267 mg	Esbriet [®]	Available	Completed	Respiratory
52	Propylthiouracil Tablets	25 / 50 / 100 mg	Propylthiouracil, Rph Pharmaceuticals	Available	Completed	Endocrinology
53	Pyrazinamide Tablets	500 mg	Zinamide [®]	Available	Completed	Anti-Tuberculosis
54	Pyridoxine Tablets	10 / 50 mg	Pyridoxine , Wockhardt	Available	Ongoing	Vitamins /Minerals /Nutrients
55	Quetiapine Tablets	25 / 100 / 200 / 300 mg	Seroquel [®]	Available	Completed	Central Nervous System
56	Rasagiline Tablets	1 mg	Azilect [®]	Available	Completed	Central Nervous System
57	Rivaroxaban Tablets	2.5 / 10 / 15 / 20 mg	Xarelto [®]	Available	Completed	Cardiology
58	Rizatriptan OD Tablets	5 / 10 mg	Maxalt [®]	Available	Completed	Central Nervous System
59	Rosuvastatin Tablets	5 / 10 / 20 / 40 mg	Crestor [®]	Available	Completed	Cardiology
60	Sacubitril +Valsartan Tablets	24+26 / 49+51 / 97+103 mg	Entresto [®]	Available	Ongoing	Cardiology

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
61	Sildenafil Tablets	20 / 25 / 50 / 100 mg	Revatio®, Viagra®	Available	Completed	Urology
62	Sitagliptin Tablets	25 / 50 / 100 mg	Januvia®	Available	Completed	Diabetology
63	Sitagliptin + Metformin Tablets	50+850 / 50+1000 mg	Janumet®	Available	Completed	Diabetology
64	Solifenacin Tablets	5 / 10 mg	Vesicara®	Available	Completed	Urology
65	Tamsulosin Prolonged Release Capsules	0.4 mg	Flomax Relief®	Available	Completed	Urology
66	Tenofovir Tablets	245 mg	Viread®	Available	Completed	Anti-Retroviral
67	Tenofovir + Emtricitabine Tablets	245+200 mg	Truvada®	Available	Completed	Anti-Retroviral
68	Tenofovir + Emtricitabine + Efavirenz Tablets	245+200+600 mg	Atripla®	Available	Completed	Anti-Retroviral
69	Ticagrelor Tablets	60 / 90 mg	Brilique®	Available	Completed	Cardiology
70	Tolterodine Prolonged Release Capsules	2 / 4 mg	Detrusitol XI®	Available	Completed	Urology
71	Valsartan Tablets	40 / 80 / 160 / 320 mg	Diovan®	Available	Completed	Cardiology
72	Varenicline Tablets	0.5 / 1 / 0.5+1 mg	Champix®	Available	Completed	Smoking Cessation
73	Vildagliptin Tablets	50 mg	Galvus®	Available	Completed	Diabetology
74	Vildagliptin + Metformin Tablets	50+850 / 50+1000 mg	Eucreas®	Available	Completed	Diabetology
75	Vortioxetine Tablets	5 / 10 / 15 / 20 mg	Brintellix®	Available	Ongoing	Central Nervous System

Upcoming Dossier

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
1	Rifaximin Tablets	550 mg	Xifaxanta®	Q3,2026	Jul, 2027	Gastroenterology
2	Empagliflozin + Linagliptin Tablets	10+5mg / 25+5mg	Glyxambi	Q4,2026	Dec, 2026	Diabetology
3	Rifaximin Tablets	200 mg	Spiraxin®	Q4,2026	Feb, 2027	Hepatic Encephalopathy
4	Lacosamide Oral Solution	10mg/ml	Vimpat®	Q4,2026		Central Nervous System
5	Enzalutamide Tablets	40 / 80 mg	Xtandi®	Q1,2027	Jan, 2027	Oncology

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
6	Inosine Pranobex Tablets	500 mg	Isoprinosine®	Q1,2027		Anti-Viral
7	Mexiletine Capsule	200 mg	Mexitil	Q1,2027		Antiarrhythmic
8	Perindopril + Indapamide + Amlodipine Tablets	5+1.25+10 / 10+2.5+10 / 5+1.25+5 / 10+2.5+5 mg	Triplixam®	Q1,2027		Cardiology
9	Perindopril Arginine Tablets	2.5 / 5 / 10 mg	Coversyl®	Q1,2027	Feb, 2027	Cardiology
10	Tofacitinib Tablets	5 mg, 10 mg	Xeljanz	Q1,2027	Feb, 2027	Janus-associated kinase (JAK) inhibitors, Rheumatoid arthritis
11	Venlafaxine Extended Release Tablets	150 / 225 / 300 mg	Vandral Retard®	Q1,2027		Central Nervous System
12	Clobazam Suspension	10 mg/5 ml, 5 mg/5 ml	Frisium Tablets®	Q2, 2027	June, 2027	Central Nervous System
13	Indapamide + Perindopril Arginine Tablets	0.625+2 / 0.625+2.5 / 1.25+5 / 1.25+10 / 2.5+10 / 4 +1.25 / 2.5+8 mg	Bipreterax®	Q2, 2027		Cardiology
14	Levothyroxine Sodium Tablets	12.5 / 25 / 50/ 75 / 100 mcg	Euthyrox® - Eu Eltroxin® - Uk	Q2, 2027		Endocrinology
15	Liothyronine Tablets	5 / 10 / 20 mcg	Cytomel®	Q2, 2027		Endocrinology
16	Cariprazine Capsules	1.5 mg / 3 mg / 4.5 mg / 6 mg	Reagila ®	Q3,2027	Aug, 2027	Psycholeptics, other antipsychotics
17	Memantine Tablets	5 / 15 mg	Ebixa®	Q3,2027		Central Nervous System
18	Olaparib Tablet	100, 150 mg	Lynparza	Q3,2027		Oncology
19	Palbociclib film coated tablets	75 mg, 100 mg, 125 mg	Ibrance®	Q3,2027	Aug, 2027	Oncology
20	Perindopril + Amlodipine tablets	5+5 / 10+10 / 5+10 / 10+5 mg	Coveram®	Q3,2027	July, 2027	Cardiology
21	Ramipril Oral Solution	2.5 mg/5 ml	Tritace®	Q3,2027		Cardiology
22	Dolutegravir + Lamivudine Tablets	50+300 mg		Q4,2027	Dec, 2027	Anti-Retroviral
23	Upadacitinib Tartrate Tablet	15 mg, 30 mg, 45 mg	Rinvoq	Q3,2027		Janus-associated kinase (JAK) inhibitors, Rheumatoid arthritis

EU- Marketing Authorization List

Country	Product Name	Dosage Form	Strengths	MA Status
Italy	Apremilast	Tablets	30 mg	Available
	Irbesartan	Tablets	75 / 150 / 300 mg	Available
	Linagliptin	Tablets	5 mg	Available
	Vortioxetine	Tablets	5 / 10 / 15 / 20 mg	DCP Ongoing
	Empagliflozin + Metformin	Tablets	5+850 / 5+1000 / 12.5+850 / 12.5+1000 mg	DCP Ongoing
	Linagliptin + Metformin	Tablets	2.5+850 / 2.5+1000 mg	DCP Ongoing
	Sitagliptin + Metformin	Tablets	50+850 / 50+1000 mg	Available
Italy	Valsartan	Tablets	40 / 80 / 160 / 320 mg	Available
Portugal	Amlodipine + Valsartan	Tablets	5+80 / 5+160 / 10+160 mg	Available
	Amlodipine + Valsartan + HCTZ	Tablets	5+160+12.5 / 5+160+25 / 10+160+12.5 / 10+160+25 / 10+320+25 mg	Available
	Atomoxetine	Capsules	10 / 18 / 25 / 40 / 60 / 80 / 100 mg	Available
	Linagliptin + Metformin	Tablets	2.5+850 / 2.5+1000 mg	DCP Ongoing
	Olmesartan + Amlodipine	Tablets	20+5 / 40+5 / 40+10 mg	Available
Spain	Amlodipine + Valsartan	Tablets	5+160 / 10+160 mg	Available
	Atomoxetine	Capsules	10 / 18 / 25 / 40 / 60 / 80 / 100 mg	Available
	Empagliflozin	Tablets	10 / 25 mg	DCP Ongoing
	Sitagliptin	Tablets	25 / 50 / 100 mg	Available
	Linagliptin	Tablets	5 mg	Available
	Vortioxetine	Tablets	5 / 10 / 15 / 20 mg	DCP Ongoing
	Empagliflozin + Metformin	Tablets	5+850 / 5+1000 / 12.5+850 / 12.5+1000 mg	DCP Ongoing
	Linagliptin + Metformin	Tablets	2.5+850 / 2.5+1000 mg	DCP Ongoing
	Moxifloxacin	Tablets	400 mg	Available
	Olmesartan + Amlodipine	Tablets	20+5 / 40+5 / 40+10 mg	Available
	Rivaroxaban	Tablets	2.5 / 10 / 15 / 20 mg	Available
	Sildenafil	Tablets	25 / 50 / 100 mg	Available
	Valsartan	Tablets	40 / 80 / 160 / 320 mg	Available
	Varenicline	Tablets	0.5 / 1 / 0.5+1 mg	Available