

EU - CTD Product 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+H CTZ 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	Ongoing	Pain Management
5	Aripiprazole Tablets	5 / 10 / 15 / 30 mg	Abilify®	Available	Completed	Central Nervous System
6	Atomoxetine Capsules	10 / 18 / 25 / 40 / 60 / 80 / 100 mg	Strattera®	Available	Completed	Central Nervous System
7	Canagliflozin tablets	100 / 300 mg	Invokana®	Available	Q2, 2026	Diabetology
8	Carbimazole Tablets	5 / 10 / 15 / 20 mg	Neomercazole®	Available	Completed	Endocrinology
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	Pain Management
13	Dapagliflozin Tablets	5 / 10 mg	Forxiga®	Available	Completed	Diabetology
14	Dapsone Tablets	25 / 50 / 100 mg	Dapsone (50 mg) Accord Barnstaple, Dapsone (100 mg) Actavis Barnstaple from UK	Available	Completed	Anti-Infective
15	Dimethyl Fumarate GR Capsules	120 / 240 mg	Tecfidera®	Available	Completed	Pain Management
16	Dolutegravir Tablets	50mg	Tivicay®	Q2, 2026	March, 2026	Anti-Retroviral
17	Donepezil OD Tablets	5 / 10 mg	Aricept Evess®	Available	Completed	Central Nervous System
18	Donepezil Tablets	5 / 10 mg	Aricept®	Available	Completed	Central Nervous System

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
19	Empagliflozin Tablets	10 / 25 mg	Jardiance®	Available	October, 2025	Diabetology
20	Escitalopram Tablets	5 / 10 / 20 mg	Cipralex®	Available	Completed	Central Nervous System
21	Febuxostat Tablets	80 / 120 mg	Adenuric®	Available	Completed	Central Nervous System
22	Irbesartan Tablets	75 / 150 / 300 mg	Aprovel®	Available	Completed	Cardiology
23	Irbesartan+HCTZ Tablets	150+12.5 / 300+12.5 / 300+25 mg	Coaprovel®	Available	Completed	Cardiology
24	Isoniazid Tablets	100 mg	Isoniazid, Rph Pharmaceuticals	Available	Completed	Anti-Tuberculosis
25	Lacosamide Tablets	50 / 100 / 150 / 200 mg	Vimpat®	Available	Completed	Central Nervous System
26	Lamivudine+Abacavir Tablets	300+600 mg	Kivexa®	Available	Completed	Anti-Retroviral
27	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
28	Levodropropizine Syrup	60 mg / 10 ml	Levopront, Dompe Farmaceutici	Available	Completed	Respiratory
29	Levofloxacin Tablets	250 / 500 mg	Tavanic®	Available	Completed	Anti-Infective
30	Linagliptin Tablets	5 mg	Trajenta®	Available	Ongoing	Diabetology
31	Linagliptin+Metformin Tablets	2.5+850 / 2.5+1000 mg	Jentadueto®	Available	Ongoing	Diabetology
32	Lamivudine Tablets	100 / 150 / 300 mg	Epivir®-300/150, Zeffix®-100	Available	Ongoing	Anti-Retroviral
33	Memantine HCL Tablets	10 / 20 mg	Ebixa®	Available	Completed	Central Nervous System
34	Memantine Oral solution	10 mg/ml (5 mg/pump)	Ebixa®	Available	Completed	Central Nervous System
35	Moxifloxacin Tablets	400 mg	Avelox®	Available	Completed	Anti-Infective
36	Nebivolol Tablets	1.25 / 2.5 / 5 / 10 mg	Nebilet®	Available	Completed	Cardiology
37	Nortriptyline Tablets	10 / 25 / 50 mg	Allegron, King Pharma, UK	Available	Completed	Central Nervous System

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
38	Olmesartan Tablets	10 / 20 / 40 mg	Olmotec®	Available	Completed	Cardiology
39	Olmesartan+Amlodipine Tablets	20+5 / 40+5 / 40+10 mg	Sevikar®	Available	Completed	Cardiology
40	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
41	Olmesartan+HCTZ Tablets	20+12.5 / 20+25 / 40+12.5 / 40+25 mg	Olmotec HCT®	Available	Completed	Cardiology
42	Pantoprazole Gastro Resistant Tablets	20 / 40 mg	Protium®	Available	Completed	Gastroenterology
43	Pirfenidone Capsules	267 mg	Esbriet®	Available	Completed	Respiratory
44	Propylthiouracil Tablets	25 / 50 / 100 mg	Propylthiouracil, RPH Pharmaceuticals	Available	Completed	Endocrinology
45	Pyrazinamide Tablets	500 mg	Zinamide®	Available	Completed	Anti-Tuberculosis
46	Pyridoxine Tablets	10 / 50 mg	Pyridoxin, Wockhardt	Available	Ongoing	Antiemetic
47	Quetiapine Tablets	25 / 100 / 200 / 300 mg	Seroquel®	Available	Completed	Central Nervous System
48	Rasagiline Tablets	1 mg	Azilect®	Available	Completed	Central Nervous System
49	Rivaroxaban Tablets	2.5 / 10 / 15 / 20 mg	Xarelto®	Available	Completed	Cardiology
50	Rizatriptan OD Tablets	5 / 10 mg	Maxalt®	Available	Completed	Central Nervous System
51	Rosuvastatin Tablets	5 / 10 / 20 / 40 mg	Crestor®	Available	Completed	Cardiology
52	Sacubitril +Valsartan Tablets	24+26 / 49+51 / 97+103 mg	Entresto®	Available	Ongoing	Cardiology
53	Sildenafil Tablets	20 / 25 / 50 / 100 mg	Revatio®, Viagra®	Available	Completed	Urology
54	Sitagliptin Tablets	25 / 50 / 100 mg	Januvia®	Available	Completed	Diabetology
55	Sitagliptin+Metformin Tablets	50+850 / 50+1000 mg	Janumet®	Available	Completed	Diabetology
56	Solifenacin Tablets	5 / 10 mg	Vesicara®	Available	Ongoing	Urology
57	Tamsulosin Prolonged Release Capsules	0.4 mg	Flomax Relief®	Available	Completed	Urology
58	Tenofovir Tablets	245 mg	Viread®	Available	Completed	Anti-Retroviral

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
59	Tenofovir+Emtricitabine Tablets	245+200 mg	Truvada®	Available	Completed	Anti-Retroviral
60	Tenofovir+Emtricitabine+Efavirenz Tablets	245+200+600 mg	Atripla®	Available	Completed	Anti-Retroviral
61	Ticagrelor Tablets	60 / 90 mg	Brilique®	Available	Completed	Cardiology
62	Tolterodine Prolonged Release Capsules	2 / 4 mg	Detrusitol XL®	Available	Completed	Urology
63	Valsartan Tablets	40 / 80 / 160 / 320 mg	Diovan®	Available	Completed	Cardiology
64	Varenicline Tablets	0.5 / 1 / 0.5+1 mg	Champix®	Available	Completed	Smoking Cessation
65	Vildagliptin Tablets	50 mg	Galvus®	Available	Completed	Diabetology
66	Vildagliptin+Metformin Tablets	50+850 / 50+1000 mg	Eucreas®	Available	Completed	Diabetology

Upcoming Dossier

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
67	Clobazam Suspension	10 mg/5 ml, 5 mg/5 ml	T-Onfi®	-	-	Central Nervous System
68	Clopidogrel+Aspirin Tablets	75+75 / 75+100 mg	Duoplavin	Q4, 2025	-	Cardiology
69	Dapagliflozin+Metformin Tablets	5+850 / 5+1000 mg	Xigduo®	Q1, 2026	March, 2026	Diabetology
70	Dutasteride Capsules	0.5 mg	Avodart®	Q2, 2026	-	Urology
71	Empagliflozin+Metformin Tablets	5+850 / 5+1000 / 12.5+850 / 12.5+1000 mg	Synjardy®	Q1, 2026	May, 2026	Diabetology
72	Enzalutamide Tablets	40 / 80 mg	Xtandi®	Q3, 2026	-	Anti-Retroviral
73	Gabapentine Oral Solution	50 mg/ml	Neurotine®	-	-	Central Nervous System
74	Inosine Pranobex Tablets	500 mg	Isoprinosin®	-	-	Anti-Viral
75	Lenalidomide capsule	2.5, 5, 7.5, 10, 15, 20, 25 mg	Revlimid®	Q2, 2026	June, 2026	Anti-Retroviral

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
76	Levothyroxine tablets	25 / 50 / 75 / 88 / 100 / 112 / 125 / 137 / 150 / 175 / 200 mcg	Euthyrox®	Q1, 2026	March, 2026	Endocrinology
77	Linezolid Tablets	600mg	Zyvox®	Q1, 2026	-	Anti-bacterial
78	Mesalamine DR Tablets	1200 mg	Mezavant®	-	-	Anti-inflammatory
79	Nintedanib Capsule	100 / 150 mg	Ofev®	Q2, 2026	May, 2026	Respiratory
80	Pomalidomide Capsule	1 / 2 / 3 / 4 mg	Pomalyst®	Q3, 2026	August, 2026	Anti-Retroviral
81	Rifaximin Tablets	200 mg	Spiraxin®	Q1, 2026	April, 2026	Anti-bacterial
82	Rifaximin Tablets	550 mg	Spiraxin®	Q1, 2026	April, 2026	Anti-bacterial
83	Vortioxetine Tablets	5 / 10 / 15 / 20 mg	Brintellix®	Q2, 2026	May, 2026	Central Nervous System

Under-Development Products

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
1	Aripiprazole Tablets	20 mg	Abilify®	—	—	Central Nervous System
2	Azithromycin Oral Suspension	100mg/5 ml , 200mg/5mL	Zithromax®	—	—	Antibiotic
3	Cholestyramine Oral Powder	4 gm	Questran light 4gm/sachet powder for oral suspension	—	—	Gastroenterology
4	Clopidogrel Film Coated Tablets	300 mg	Plavix®	—	—	Cardiology
5	Colestyramine Oral Powder	4 gm	Quantalan® - EU Questran® - UK	—	—	Cardiology
6	Dutasteride +Tamsulosine soft gel capsules	0.4+0.5mg	Duodart®	—	—	Urology
7	Emtricitabine+Tenofovir Alafenamide Fumarate Tablets	200+10 / 200+25 mg	Descovy®	—	—	Anti - Retroviral
8	Escitalopram Tablets	15 mg	Cipratex®	—	—	Central Nervous System
9	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®	—	—	Cardiology
10	Levothyroxine Sodium Tablets	12.5 / 25 / 50/ 75 / 100 mcg	Eltroxin® - UK	—	—	Endocrinology

Sr No.	Product	Strength	Reference Product	Dossier Availability	DCP Status	Therapy
11	Memantine Tablets (Germany)	5 / 15 mg	Ebixa®	—	—	Central Nervous System
12	Mesalamine Powder (retard)(EU)	1 / 2 / 4 g	Pentasa®	—	—	Anti-inflammatory
13	Mesalamine Powder (retard)(EU)	1 / 1.5 / 3 gm	Salofalk®	—	—	Anti-inflammatory
14	Mesalamine SR tablets 500 mg, 1000 mg (EU)	500 / 1000 mg	Pentasa SR®	—	—	Anti-inflammatory
15	Nitrofurantoin Capsules	100 mg	Macrochantin® / Macrobid® (100 mg)	—	—	Anti-Infective
16	Perindopril + Amlodipine tablets	5+5 / 10+10 / 5+10 / 10+5 mg	Coveram®	—	—	Cardiology
17	Perindopril + Indapamide + Amlodipine Tablets	5+1.25+10 / 10+2.5+10 / 5+1.25+5 / 10+2.5+5 mg	Triplixam®	—	—	Cardiology
18	Perindopril Arginine Tablets	2.5 / 5 / 10 mg	Coversyl®	—	—	Cardiology
19	Pramipexole Extended Release Tablets	0.375 / 0.75 / 1.5 / 2.25 / 3.0 / 3.75 / 4.50 mg	Sifrol®	—	—	Central Nervous System
20	Pramipexole Prolonged Release Tablets	0.26 / 0.52 / 1.05 / 1.57 / 2.1 / 2.62 / 3.15 mg	Sifrol®	—	—	Central Nervous System
21	Ramipril Oral Solution	2.5 mg/5 ml	Tritac®	—	—	Cardiology
22	Tamsulosin PR tablets 0.4 mg (EU)	0.4 mg	Omnice®	—	—	Urology
23	Valsartan Flim Coated Tablets	120 mg	Diovan®	—	—	Cardiology
24	Venlafaxine Extended Release Tablets	150 / 225 / 300 mg	Vandral Retard®	—	—	Central Nervous System

EU- Marketing Authorization List

Country	Product Name	Dosage Form	Strengths	MA Status
Italy	Apremilast	Tablets	30 mg	DCP Ongoing
	Irbesartan	Tablets	75 / 150 / 300 mg	Available
	Linagliptin	Tablets	5 mg	DCP Ongoing
	Linagliptin + Metformin	Tablets	2.5+850 / 2.5+1000 mg	DCP Ongoing
	Sitagliptin + Metformin	Tablets	50+850 / 50+1000 mg	Available
Malta	Valsartan	Tablets	40 / 80 / 160 / 320 mg	Available
France	Apremilast	Tablets	30 mg	DCP Ongoing
Poland	Linagliptin	Tablets	5 mg	DCP Ongoing
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
	Olmesartan + Amlodipine + HCTZ	Tablets	20+5+12.5 / 40+5+12.5 / 40+5+25 / 40+10+12.5 / 40+10+25 mg	Available
	Tenofovir + Emtricitabine	Tablets	245+200 mg	Available
Spain	Amlodipine + Valsartan	Tablets	5+160 / 10+160 mg	Available
	Apixaban	Tablets	2.5 / 5 mg	Available
	Apremilast	Tablets	30 mg	DCP Ongoing
	Atomoxetine	Capsules	10 / 18 / 25 / 40 / 60 / 80 / 100 mg	Available
	Linagliptin	Tablets	5 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
	Tolterodine ER	Capsules	2 / 4 mg	Available
	Valsartan	Tablets	40 / 80 / 160 / 320 mg	Available
	Varenicline	Tablets	0.5 / 1 / 0.5+1 mg	Available