

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+ 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	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	Carbimazole Tablets	5 / 10 / 15 / 20 mg	Neomercazole®	Available	Completed	Endocrinology
8	Celecoxib Capsules	100 / 200 mg	Celebrex®	Available	Completed	Pain Management
9	Cinacalcet Tablets	30 / 60 / 90 mg	Mimpara®	Available	Completed	Endocrinology
10	Clopidogrel Tablets	75 mg	Plavix®	Available	Completed	Cardiology
11	Colchicine Tablets	0.5 / 1 mg	Colchicine, Wockhardt	Available	Completed	Pain Management
12	Dapagliflozin Tablets	5 / 10 mg	Forxiga®	Available	Completed	Diabetology
13	Dapsone Tablets	25 / 50 / 100 mg	Daposne (50 mg) Accord Barnstaple, Dapsone (100 mg) Actavis Barnstaple from UK	Available	UK National - Ongoing	Anti-Infective

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14	Dimethyl Fumarate Capsules	120 / 240 mg	Tecfidera®	Available	Completed	Pain Management
15	Donepezil OD Tablets	5 / 10 mg	Aricept Evess®	Available	Completed	Central Nervous System
16	Donepezil Tablets	5 / 10 mg	Aricept®	Available	Completed	Central Nervous System
17	Escitalopram Tablets	5 / 10 / 20 mg	Ciprallex®	Available	Completed	Central Nervous System
18	Febuxostat Tablets	80 / 120 mg	Adenuric®	Available	Completed	Central Nervous System
19	Irbesartan Tablets	75 / 150 / 300 mg	Aprovel®	Available	Completed	Cardiology
20	Irbesartan+HCTZ Tablets	150+12.5 / 300+12.5 / 300+25 mg	Coaprovel®	Available	Completed	Cardiology
21	Isoniazid Tablets	100 mg	Isoniazid, Rph Pharmaceuticals	Available	UK National	Anti-Tuberculosis
22	Lacosamide Tablets	50 / 100 / 150 / 200 mg	Vimpat®	Available	Completed	Central Nervous System
23	Lamivudine+Abacavir Tablets	300 + 600 mg	Kivexa®	Available	Completed	Anti-Retroviral
24	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
25	Levodropropizine Syrup	60 mg/10 ml	Levopront, Dompe Farmaceutici	Available	Completed	Respiratory
26	Levofloxacin Tablets	250 / 500 mg	Tavanic®	Available	Completed	Anti-Infective
27	Linagliptin Tablets	5 mg	Trajenta®	Available	Ongoing	Diabetology
28	Linagliptin+Metformin Tablets	2.5+850 / 2.5+1000 mg	Jentadueto®	Available	Ongoing	Diabetology
29	Memantine HCL Tablets	10 / 20 mg	Ebixa®	Available	Completed	Central Nervous System

Sr No.	Product	Strength	Reference product	Dossier Availability	DCP Status	Therapy
30	Memantine Oral Drops	10 mg/ml (5 mg/pump)	Ebixa®	Available	Completed	Central Nervous System
31	Moxifloxacin Tablets	400 mg	Avelox®	Available	Completed	Anti-Infective
32	Nebivolol Tablets	1.25 / 2.5 / 5 / 10 mg	Nebilet®	Available	Completed	Cardiology
33	Nortriptyline Tablets	10 / 25 / 50 mg	Allgegron, King Pharma, UK	Available	Completed	Central Nervous System
34	Olmesartan Tablets	10 / 20 / 40 mg	Olmetec®	Available	Completed	Cardiology
35	Olmesartan+Amlodipine Tablets	20+5 / 40+5 / 40+10 mg	Sevikar®	Available	Completed	Cardiology
36	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
37	Olmesartan+HCTZ Tablets	20+12.5 / 20+25 / 40+12.5 / 40+25 mg	Olmetec HCT®	Available	Completed	Cardiology
38	Pantoprazole Gastro Release Tablets	20 / 40 mg	Protium®	Available	Completed	Gastroenterology
39	Phenytoin Sodium Capsules	25 / 50 / 100 mg	Phenytoin Sodium, Flynn Pharma	Available	Ongoing	Central Nervous System
40	Pirfenidone Capsules	267 mg	Esbriet®	Available	Completed	Respiratory
41	Propylthiouracil Tablets	25 / 50 / 100 mg	Propylthiouracil, Rph Pharmaceuticals	Available	Completed	Endocrinology
42	Pyrazinamide Tablets	500 mg	Zinamide®	Available	Completed	Anti-Tuberculosis
43	Quetiapine Tablets	25 / 100 / 200 / 300 mg	Seroquel®	Available	Completed	Central Nervous System
44	Rasagiline Tablets	0.5 / 1 mg	Azilect®	Available	Completed	Central Nervous System
45	Rivaroxaban Tablets	2.5 / 10 / 15 / 20 mg	Xarelto®	Available	Completed	Cardiology
46	Rizatriptan OD Tablets	5 / 10 mg	Maxalt®	Available	Completed	Central Nervous System
47	Rosuvastatin Tablets	5 / 10 / 20 / 40 mg	Crestor®	Available	Completed	Cardiology
48	Sildenafil Tablets	20 / 25 / 50 / 100 mg	Revatio®, Viagra®	Available	Completed	Urology

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49	Sitagliptin Tablets	25 / 50 / 100 mg	Januvia®	Available	Ongoing	Diabetology
50	Sitagliptin+Metformin Tablets	50+850 / 50+1000 mg	Janumet®	Available	Completed	Diabetology
51	Solifenacin Tablets	5 / 10 mg	Vesicara®	Available	Ongoing	Urology
52	Tamsulosin Extended Release Capsules	0.4 mg	Flomax Relief®	Available	Completed	Urology
53	Tenofovir Tablets	245 mg	Viread®	Available	Completed	Anti-Retroviral
54	Tenofovir+Emtricitabine Tablets	245+200 mg	Truvada®	Available	Completed	Anti-Retroviral
55	Tenofovir+Emtricitabine+Efavirenz Tablets	245+200+600 mg	Atripla®	Available	Completed	Anti-Retroviral
56	Ticagrelor Tablets	60 / 90 mg	Brilique®	Available	Completed	Cardiology
57	Tolterodine Extended Release Capsules	2 / 4 mg	Detrusitol XL®	Available	Completed	Urology
58	Valsartan Tablets	40 / 80 / 160 / 320 mg	Diovan®	Available	Completed	Cardiology
59	Varenicline Tablets	0.5 / 1 / 0.5+1 mg	Champix®	Available	Ongoing	Smoking Cessation
60	Vildagliptin Tablets	50 mg	Galvus®	Available	Completed	Diabetology
61	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
62	Clobazam Suspension	10 mg/5 ml, 5 mg/5 ml	T-Onfi®	Q1, 2025	—	Central Nervous System
63	Dapagliflozin+Metformin Tablets	5+850 / 5+1000 mg	Xigduo®	Q1, 2025	—	Diabetology
64	Dutasteride Capsules	0.5 mg	Adalat®	Q4, 2024	—	Urology
65	Empagliflozin+Metformin Tablets	5+850 / 5+1000 / 12.5+850 / 12.5+1000 mg	Synjardy®	Q1, 2025	—	Diabetology
66	Gabapentine Oral Solution	50 mg/ml	Neurotine®	Q4, 2024	—	Central Nervous System
67	Inosine Pranobex Tablets	500 mg	Isoprinosin®	Q2, 2025	—	Anti-Viral
68	Ivabradine Hydrochloride Tablets	2.5 / 5 / 7.5 mg	Troporalan®	Q2, 2025	—	Cardiology

Upcoming Dossier

Sr No.	Product	Strength	Reference product	Dossier Availability	DCP Status	Therapy
69	Lamivudine Tablets	100 / 150 / 300 mg	Epivir®-300/150, Zeffix®-100	Q3, 2024	—	Anti-Retroviral
70	Phenytoin Sodium Capsules	300 mg	Phenytoin Sodium, Flynn Pharma	Q4, 2024	—	Central Nervous System
71	Pyridoxine Tablets	10 / 50 mg	N/A	Q4, 2024	—	Vitamins/Minerals/Nutrients
72	Rifaximin Tablets	200 / 550 mg	Xifaxan®	Q1, 2025	—	Anti-Infective

Under-Development Products

Sr No.	Product	Strength	Reference product	Dossier Availability	DCP Status	Therapy
1	Aripiprazole Tablets	20 mg	Abilify®	—	—	Central Nervous System
2	Bisoprolol+HCTZ Tablets	2.5+6.25 / 5+6.25 / 5+12.5 / 10+6.25 / 10+12.5 / 10+25 mg	Emcoretic Mitis® / Emcorectic®	—	—	Cardiology
3	Bisoprolol Fumarate Tablets	1.25 / 2.5 / 3.75 / 5 / 7.5 / 10 mg	Concor® (Germany)	—	—	Cardiology
4	Colestyramine Oral Powder	4 gm	Quantalan® - EU Questran® - UK	—	—	Cardiology
5	Clopidogrel Film Coated Tablets	300 mg	Plavix®	—	—	Cardiology
6	Dabigatran Capsules	75 / 150 mg	Pradaxa®	—	—	Cardiology
7	Darifenacin Extended Release Tablets	7.5 / 15 mg	Emselex®	—	—	Urology
8	Emtricitabine+Tenofovir Alafenamide Fumarate Tablets	200+10 / 200+25 mg	Descovy®	—	—	Anti - Retroviral
9	Escitalopram Tablets	15 mg	Elicea®	—	—	Central Nervous System
10	Fluoxetine Oral Liquid	20 mg/5 ml	Prozac OS®	—	—	Central Nervous System
11	Indapamide Tablets	2.5 mg	Nartrilix®	—	—	Cardiology
12	Indapamide Extended Release Tablets	1.5 mg	Nartrilix®	—	—	Cardiology
13	Indapamide+Perindopril Arginine Tablets	0.625+2.5/ 1.25+5 / 1.25+10 / 2.5+10 mg	Bipreterax®	—	—	Cardiology

Under-Development Products

Sr No.	Product	Strength	Reference product	Dossier Availability	DCP Status	Therapy
14	Levothyroxine Sodium Tablets	12.5 / 25 / 100 / 200 mcg	Euthyrox® - EU Eltroxin® - UK	—	—	Endocrinology
15	Linaclotide Capsules	145 / 290 mcg	Linzess®	—	—	Gastroenterology
16	Liothyronine Tablets	20 mcg	Liothyronin Sodium, Mercury Pharma	—	—	Endocrinology
17	Memantine Tablets (Germany)	5 / 15 mg	Ebixa®	—	—	Central Nervous System
18	Montelukast Chewable Tablets (Germany)	4 / 5 mg	Singulair®	—	—	Respiratory
19	Montelukast Powder (Germany)	4 gm	Singulair Mini UK - Singulair Padeatric	—	—	Respiratory
20	Nitrofurantoin Capsules	25 / 50 / 100 mg	Macrochantin® / Macrobid® (100 mg)	—	—	Anti-Infective
21	Nitrofurantoin Suspension	25 mg/5 ml	Furadantin®	—	—	Anti-Infective
22	Pramipexole Extended Release Tablets	0.375 / 0.75 / 1.5 / 2.25 / 3.0 / 3.75 / 4.50 mg	Sifrol®	—	—	Central Nervous System
23	Pramipexole Prolonged Release Tablets	0.26 / 0.52 / 1.05 / 1.57 / 2.1 / 2.62 / 3.15 mg	Sifrol®	—	—	Central Nervous System
24	Quetiapine Flim Coated Tablets	50 / 150 / 400 mg	Seroquel®	—	—	Central Nervous System
25	Ramipril Oral Solution	2.5 mg/5 ml	Tritac®	—	—	Cardiology
26	Sacubitril + Valsartan Tablets	24+26 / 49+51 / 97+103 mg	Entresto®	—	—	Cardiology
27	Sucroferric Oxyhydroxide Chewable Tablets	500 mg	Velphoro® (US)	—	—	Urology
28	Trifluoperazine Oral Liquid	1 mg/5 ml, 5 mg/5 ml	Stelazine®	—	—	Central Nervous System
29	Ursodiol Capsules	250 mg	Ursofalk®	—	—	Urology
30	Valsartan Flim Coated Tablets	120 mg	Diovan®	—	—	Cardiology
31	Venlafaxine Extended Release Tablets	75 / 150 / 225 / 300 mg	Vandral Retard®	—	—	Central Nervous System