Pharmathen

GLOBAL

PRODUCT CATALOGUE

2025

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1. COMPANY PROFILE

Pharmathen is one of the leading developers of complex drug delivery systems and advanced formulations, leveraging proprietary in-house technologies to improve patient compliance and make high-quality, affordable medicines accessible to global markets.

Today, we proudly serve a broad network of more than 250 partners in over 90 countries across Europe, North America, South America, the Middle East, Asia, Australasia, and Southern Africa. Our diverse portfolio includes over 100 products, supported by one of the industry's most extensive and advanced pipelines of Long-Acting Injectables (LAI) and other complex dosage forms, such as peptides, sustained-release oral solids, and ophthalmic formulations. These are produced in our US FDA and EU-approved manufacturing facilities in Greece and through our global contract manufacturing network.

MANUFACTURING
SITE SAPES RODOPI

Ranked among the top 50 pharmaceutical research companies in Europe, Pharmathen is also one of the largest private-sector investors in research and development in Greece, consistently investing close to €50 million annually. These continuous investments keep us at the forefront of innovation, enabling us to expand market access and strengthen partnerships worldwide, bringing more affordable, high-quality medicines to patients everywhere. We proudly employ more than 1,600 people representing over 24 nationalities across 9 locations. Our shared commitment to creativity, ethics, and reliability drives our vision of “making a difference in people’s lives.”

HEADQUARTERS
MAROUSSI

2. PRODUCT PORTFOLIO

a) Long Acting Injectables

With the foundation of the three key in house technologies, all of which are validated to commercial scale, these formulations are geared to support the improvement and effectiveness of drug therapy and patient compliance.

PRODUCT (Reference drug)	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
ARIPIPRAZOLE (Abilify Maintena®)	Long-acting injectable Nanosuspension	300mg/vial 400mg/vial	Schizophrenia	Under approval (EU)
		300mg/syringe 400mg/syringe		Under development
ARIPIPRAZOLE LAUROXIL (Aristada™)	Long-acting injectable Nanosuspension	441mg/syringe 662mg/syringe 882mg/syringe 1064mg/syringe	Schizophrenia	Under development
ARIPIPRAZOLE LAUROXIL INITIO (Aristada Initio®)	Long-acting injectable Nanosuspension	675mg/syringe	Schizophrenia	Under development
BUPRENORPHINE (Buvidal®(EU), Brixadi®(US))	Long-acting injectable In situ forming liquid crystalline gel (FluidCrystal formulation technology by Camurus)	WEEKLY: 8 mg/0.16 ml 16 mg/0.32ml 24 mg/0.48 ml 32 mg/0.64 ml MONTHLY: 64 mg/0.18 ml 96 mg/0.27 ml 128 mg/0.36 ml	Moderate to severe opioid use disorder	Under development
LANREOTIDE (Somatuline Autogel®)	Long-acting injectable Nano-gel	60mg/syringe 90mg/syringe 120mg/syringe	Acromegaly; Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	Commercialized

PRODUCT (Reference drug)	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
LEUPROLIDE (Enantone®)	Long-acting injectable PLGA/PLA microparticles	Dual Chambered Syringe 3.75mg/syringe (1 month)	Prostate cancer, Endometriosis, Fibroids, Breast cancer	Under development
		Dual Chambered Syringe 11.25mg/syringe (3 month)	Prostate cancer, Endometriosis, Breast cancer	Under development
		Dual Chambered Syringe 30mg/syringe (6 month)	Prostate cancer	Under development
NALTREXONE (Vivitrol®)	Long-acting injectable PLGA microparticles	380mg/vial	Alcohol dependence; Opioid dependence	US approved
OCTREOTIDE (Sandostatin®)	Long-acting injectable PLGA microparticles	10mg/vial 20mg/vial 30mg/vial	Acromegaly, Severe diarrhea/ flushing episodes (associated with metastatic carcinoid tumors), watery diarrhea (assosiated with VIP-secreting tumors)	Commercialized
PALIPERIDONE PALMITATE 1M (Xeplion®)	Long-acting injectable Nanosuspension	25mg/syringe 50mg/syringe 75mg/syringe 100mg/syringe 150mg/syringe	Schizophrenia	Commercialized
PALIPERIDONE PALMITATE 3M (Trevicta®)	Long-acting injectable Nanosuspension	175mg/syringe 263mg/syringe 350mg/syringe 525mg/syringe	Schizophrenia	EU Submitted
RISPERIDONE (Risperdal Consta®)	Long-acting injectable PLGA microparticles	12.5mg/vial 25mg/vial 37.5mg/vial 50mg/vial	Schizophrenia	Commercialized
TRIAMCINOLONE ACETONIDE (Zilretta®)	Long-acting injectable PLGA microparticles	32mg/vial	Osteoarthritis pain of the knee	Under development

b) Ophthalmic Formulations

Supporting the advancement in the eye-care market and treatments, through improved patient convenience and tolerance.

i. Preservative Free Ophthalmics in multi dose vials

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
BIMATOPROST PRESERVATIVE FREE	Eye drops solution multi dose container	0.3mg/ml	Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults	EU Approved
BIMATOPROST TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	0.3mg/ml 5mg/ml	Reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues	EU Approved
BRIMONIDINE PRESERVATIVE FREE	Eye drops solution multi dose container	2mg/ml	Reduction of elevated intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension	Dossier Ready
BRIMONIDINE TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	2mg/ml 5mg/ml	Reduction of intraocular pressure (IOP) in patients with chronic open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers	EU Approved
CHLORAMPHENICOL PRESERVATIVE FREE	Eye drops solution multi dose container	5mg/ml	Topical antibacterial in the treatment of superficial ocular infections (also indicated in adults and children for the treatment of acute bacterial conjunctivitis)	EU Approved
DEXAMETHASONE PRESERVATIVE FREE	Eye drops solution multi dose container	1mg/ml	Treatment of non-infectious inflammatory conditions affecting the anterior segment of the eye	EU Approved
DORZOLAMIDE TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	5mg/ml 20mg/ml	Intraocular pressure elevation treatment	EU Approved

PRODUCT (reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
DORZOLAMIDE PRESERVATIVE FREE	Eye drops solution multi dose container	20mg/ml	Intraocular pressure elevation treatment	EU Approved
LATANOPROST PRESERVATIVE FREE	Eye drops solution multi dose container	0.05mg/ml	Reduction of elevated intraocular pressure	EU Approved
LATANOPROST PRESERVATIVE FREE 2 months treatment	Eye drops solution multi dose container	0.05mg/ml	Reduction of elevated intraocular pressure	EU Approved
LATANOPROST TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	0.05mg/ml 5mg/ml	Reduction of intraocular pressure (IOP) in patients with open angle glauco-ma and ocular hypertension	EU Approved
LATANOPROST TIMOLOL PRESERVATIVE FREE 2 months treatment	Eye drops solution multi dose container	0.05mg/ml 5mg/ml	Reduction of intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension	EU Approved
TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	2.5mg/ml 5mg/ml	Elevated intraocular pressure decrease	EU Approved
TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	40mcg/ml	Elevated intraocular pressure decrease	EU Approved
TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	30mcg/ml	Elevated intraocular pressure decrease	EU Approved
TRAVOPROST TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	40mcg/ml 5mg/ml	Elevated intraocular pressure decrease	EU Approved

ii. Preserved ophthalmic finished formulations in multi dose vials.

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
BIMATOPROST (Lumigan®)	Eye drops solution	0.1mg/ml 0.3mg/ml	Reduction of elevated intraocular pressure in open-angle glaucoma or ocular hypertension	EU Approved
BRINZOLAMIDE (Azopt®)	Eye drops, suspension	10mg/ml	Intraocular Pressure Elevation Treatment in Ocular Hypertension & in Open-angle Glaucoma	EU Approved
BRINZOLAMIDE BRIMONIDINE (Simbrinza®)	Eye drops, suspension	10mg/ml 2mg/ml	Reduction of elevated intraocular pressure in open-angle glaucoma or ocular hypertension	EU Approved
BRINZOLAMIDE TIMOLOL (Azarga®)	Eye drops, suspension	10mg/ml 5mg/ml	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma	EU Approved
DORZOLAMIDE (Trusopt®)	Eye drops solution	20mg/ml	Intraocular pressure elevation treatment	EU Approved
DORZOLAMIDE TIMOLOL (Cosopt®)	Eye drops solution	20mg/ml 5mg/ml	Intraocular pressure elevation treatment	EU Approved
MOXIFLOXACIN (Vigamox®)	Eye drops solution	5mg/ml	Bacterial infections treatment	EU Approved
TRAVOPROST (Travatan®)	Eye drops solution	40mcg/ml	Elevated intraocular pressure decrease	EU Approved
TRAVOPROST (Izba®)	Eye drops solution	30mcg/ml	Elevated intraocular pressure decrease	EU Approved
TRAVOPROST TIMOLOL (Duotrav®)	Eye drops solution	40mcg/ml 5mg/ml	Elevated intraocular pressure decrease	EU Approved

c) Generic finished dosage

Driven by strong research, innovation and IP protection covering multiple therapeutic areas and market segments.

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
ALENDRONATE + CHOLECALCIFEROL (Fosavance®)	Tablets	70mg/2800IU 70mg/5600IU	Postmenopausal osteoporosis	EU Approved
APREMILAST (Otezla®)	F.C. Tablets	10mg 20mg 30mg	Treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy	EU Submitted
APREPITANT (Emend®)	Hard capsules	40mg 80mg 125mg 165mg	Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults	EU Approved
ARIPIPRAZOLE (Abilify®)	Orodispersible tablets	10mg 15mg 30mg	Schizophrenia, manic episode treatment	EU Approved
ARIPIPRAZOLE (Abilify ®)	Tablets	5mg, 10mg, 15mg, 30mg	Schizophrenia, manic episode treatment	EU Approved
ATOMOXETINE (Strattera®)	Hard capsules	10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg	Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)	EU Approved
ATORVASTATIN (Lipitor®)	F.C. Tablets	10mg, 20mg, 40mg, 80mg	Hypercholesterolemia treatment, cardiovascular disease prevention	EU Approved
CASPOFUNGIN (Cancidas®)	Powder for concentrate for solution for infusion	50mg 70mg	Invasive candidiasis, invasive aspergillosis treatment	EU Approved
CIPROFLOXACIN (Ciproxin®)	Solution for infusion	100mg/50ml 200mg/100ml 400mg/200ml	Infections treatment	EU Approved
CIPROFLOXACIN (Ciproxin®)	F.C. Tablets	250mg 500mg 750mg	Infections treatment	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
CLOPIDOGREL (Plavix®)	F.C. Tablets	75mg	Prevention of Atherothrombotic & Thromboembolic Events	EU Approved
DABIGATRAN (Pradaxa®)	Hard capsules	75mg 110mg 150mg	Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF)	EU Approved
DARUNAVIR (Prezista®)	F.C. Tablets	75mg, 150mg, 300mg, 400mg, 600mg, 800mg	Treatment of patients with human immunodeficiency virus (HIV-1)infection	EU Approved
DEFERASIROX (Exjade®)	Tablets	90mg,180mg, 360mg	Treatment of chronic iron overload due to frequent blood transfusions	EU Approved
DIMETHYL FUMARATE (Tecfidera®)	Delayed release capsules	120mg 240mg	Treatment of adult patients with relapsing remitting multiple sclerosis	Available
DULAGLUTIDE (Trulicity®)	Solution for injection in pre-filled pen	0.75mg/0.5ml 1.5mg/0.5ml 3mg/0.5ml 4.5mg/0.5ml	Type 2 Diabetes Mellitus	Under development
DULOXETINE (Cymbalta®)	Hard gastro-resistant capsules	30mg 60mg	Treatment of depression and generalized anxiety disorder. Treatment of diabetic peripheral neuropathic pain	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
ELIGLUSTAT (Cerdelga®)	Hard capsules	84mg	Long-term treatment of adult patients with Gaucher disease type 1 (GD1), who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs)	Under development
ENTECAVIR (Baraclude®)	F.C. Tablets	0.5mg 1mg	Treatment of chronic hepatitis B virus (HBV) infection	EU Approved
EPLERENONE (Inspra®)	F.C. Tablets	25mg 50mg	Beta-blockers therapy	EU Approved
ESOMEPRAZOLE (Nexium®)	Powder for solution for injection/infusion	40mg	Gastric antisecretory treatment for adults and children	EU Approved
FERRIC CARBOXYMALTOSE (Ferinject®)	Solution for injection/infusion	100mg/2ml 500mg/10ml 750mg/15ml 1.000mg/20ml	Treatment of iron deficiency	Under development
FERRIC DERISOMALTOSE (Monoferric®)	Solution for injection	100mg/1ml 500mg/5ml 1000mg/10ml	Indicated for the treatment of iron deficiency anemia (IDA) in adult patients: • who have intolerance to oral iron or have had unsatisfactory response to oral iron • who have non-hemodial-ysis dependent chronic kidney disease (NDD-CKD)	Under development
FINASTERIDE (Proscar®)	F.C. Tablets	5mg	Benign prostatic hyperplasia (BPH) treatment and control	EU Approved
FINERENONE (Kerendia®)	F.C. Tablets	10mg 20mg	Indicated for the treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults	Under development
FINGOLIMOD (Gilenya®)	Hard capsules	0.5mg	Indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
FLUCONAZOLE (Diflucan®)	Solution for infusion	50mg/25ml 100mg/50ml 200mg/100ml 400mg/200ml	Anti-infective therapy	EU Approved
FLUCONAZOLE (Diflucan®)	Hard capsules	50mg, 100mg, 150mg, 200mg	Anti-infective therapy	EU Approved
FLUVASTATIN XL (Lescol®)	Prolonged release tablets	80mg	Dyslipidemia adjunct to diet andsecondary prevention in coronary heart disease	EU Approved
GALANTAMINE (Reminyl®)	F.C. Tablets	4mg, 8mg, 12mg	Dementia of the Alzheimer type symptomatic treatment	Dossier Ready
GALANTAMINE SR (Reminyl®)	Prolonged-release hard capsules	8mg, 16mg, 24mg	Dementia of the Alzheimer type symptomatic treatment	EU Approved
IBANDRONATE (Bondronat®)	Concentrate for solution for infusion	1mg/1ml 2mg/2ml 6mg/6ml	Prevention of Skeletal Events & Treatment of Hypercalcemia	EU Approved
IBANDRONATE (Bonviva®)	F.C. Tablets ONCE A MONTH	150mg	Postmenopausal osteoporosis treatment	EU Approved
IBANDRONATE (Bondronat®)	F.C. Tablets	50mg	Prevention of Skeletal Events in Patients with Cancer	EU Approved
INCLISIRAN (Leqvio®)	Solution for injection	284 mg/1.5 ml	(siRNA) for LDL-C reduction in primary hyperlipidemia, as an adjuct to diet and statin therapy	Under Development
IRON SUCROSE (Venofer®)	Injection, for intravenous use	50mg/2.5ml, 100mg/5ml, or 200 mg/10ml (20 mg/mL) in single-dose vials	Treatment of iron deficiency anemia in patients with chronic kidney disease (CKD)	Under Development

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
ISOTRETINOIN (Roaccutane®)	Soft gel capsules	5mg, 10mg, 20mg	Severe forms of acne treatment	EU Approved
LEFLUNOMIDE (Arava®)	F.C. Tablets	10mg, 15mg 20mg, 100mg	Active rheumatoid arthritis treatment Psoriatic arthritis treatment	EU Approved
LETERMOVIR (Prevymis®)	F.C. Tablets	240mg 480mg	Indicated for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT). Letermovir is indicated for prophylaxis of CMV disease in CMV-seronegative adults who have received a kidney transplant from a CMV-seropositive donor [D+/R-]	Under Development
LEVETIRACETAM (Keppra®)	Concentrate for solution for infusion	100mg/ml	Epilepsy treatment	EU Approved
LEVETIRACETAM (Keppra®)	Oral solution	100mg/ml	Epilepsy treatment	EU Approved
LEVETIRACETAM (Keppra®)	F.C. Tablets	250mg, 500mg, 750mg, 1000mg	Epilepsy treatment	EU Approved
LEVOFLOXACIN (Tavanic®)	Solution for infusion	5mg/ml	Infections treatment	EU Approved
LEVOFLOXACIN (Tavanic®)	F.C. Tablets	250mg 500mg	Infections treatment	EU Approved
LINACLOTIDE (Constella®/EU) (Lynzess®/US)	Hard capsules	72 mcg 145 mcg 290 mcg	Indicated for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults	Under Development
LINEZOLID (Zyvoxid®)	F.C. Tablets	600mg	Nosocomial & community acquired pneumonia, complicated skin and soft tissue infections treatment	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
LIRAGLUTIDE (Victoza®)	Solution for injection in pre-filled pen	6mg/ml	Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise	EU Submitted
LIRAGLUTIDE (Saxenda®)	Solution for injection in pre-filled pen	6mg/ml	Indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of ≥30 kg/m^2 (obeseity), or ≥ 27 kg/m^2 to <30 kg/m^2 (overweight)	Under Development
LOSARTAN (Cozaar®)	F.C. Tablets	12.5mg, 25mg, 50mg, 100mg	Essential hypertension treatment	EU Approved
LOSARTAN + HCTZ (Hyzaar®, Fortzaar®)	F.C. Tablets	50/12.5mg 100/25mg	Essential hypertension treatment	EU Approved
MEROPENEM (Merrem®)	Powder for solution for injection or infusion	500mg 1g	Infections treatment	EU Approved
MIRABEGRON (Betmiga®)	Prolonged release tables	25mg 50mg	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome	Under Development
MONTELUKAST (Singulair®)	F.C. Tablets	10mg	Asthma treatment	EU Approved
MONTELUKAST (Singulair®)	Chewable tablets	4mg 5mg	Asthma treatment	EU Approved
MOXIFLOXACIN (Avelox®)	F.C. Tablets	400mg	Bacterial infections treatment	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
NETUPITANT PALONOSETRON (Akynzeo®)	Hard capsules	300mg/0.5mg	Indicated in adults for the • Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. • Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy	Under Development
NUSINERSEN (Spinraza®)	Solution for injection	12mg/5ml (2.4mg/ml)	Treatment of spinal muscular atrophy (SMA) in pediatric and adult patients	Under Development
PATISIRAN (Onpattro®)	Solution for injection	10mg base/5ml	Indicated for the treatment of hereditary transthyrtin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy	Under Development
OLANZAPINE (Zyprexa®)	Orodispersible tablets	5mg, 10mg, 15mg, 20mg	Treatment of Schizophrenia or Manic Episode bipolar disorder recurrence prevention (manic episode patients responding to therapy)	EU Approved
OLANZAPINE (Zyprexa®)	F.C. Tablets	2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg	Treatment of Schizophrenia or Manic Episode bipolar disorder recurrence prevention (manic episode patients responding to therapy)	EU Approved
OLANZAPINE (Zyprexa®)	Powder for solution for injection	10mg/vial	Treatment of Schizophrenia or Manic Episode bipolar disorder recurrence prevention (manic episode patients responding to therapy)	EU Approved
ONDANSETRON (Zofron®)	Solution for Injection	4mg/2ml 8mg/4ml	Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy and for the prevention and treatment of post-operative nausea and vomiting	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
ONDANSETRON (Zofron®)	F.C. Tablets	4mg 8mg	Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, and for the prevention of post-operative nausea and vomiting	EU Approved
PARICALCITOL (Zemplar®)	Solution for injection	5mcg/ml 10mcg/2ml 2mcg/ml 4mcg/2ml	Prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure undergoing hemodialysis	EU Approved
PRAMIPEXOLE (Mirapexin®)	Tablets	0.088mg 0.18mg 0.35mg 0.7mg 1.1mg	Treatment of the signs and symptoms of idiopathic Parkinson's disease and moderate to severe idiopathic Restless Legs Syndrome	EU Approved
PRASUGREL (HCL) (Efient®)	F.C. Tablets	5mg 10mg	Prevention of atherothrombotic events in adult patients with acute coronary syndrome	EU Approved
PREGABALIN (Lyrica®)	Hard capsules	25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg	Neuropathic pain, epilepsy and generalized anxiety disorder treatment	EU Approved
QUETIAPINE SR (Seroquel®)	Prolonged-release tablets	50mg, 150mg, 200mg, 300mg, 400mg, 600mg	Schizophrenia and bipolar disorder treatment	EU Approved
RALOXIFENE (Evista®)	F.C. Tablets	60mg	Postmenopausal osteoporosis treatment and prevention	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
RANOLAZINE (Ranexa®)	Prolonged-release tablets	375mg 500mg 750mg	Add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies	EU Approved
REPAGLINIDE (NovoNorm®)	Tablets	0.5mg 1mg 2mg	Type 2 diabetes mellitus adjunct to diet	EU Approved
RIFAXIMIN (Xifaxan®)	Tablets	200mg 550mg	200mg: Treatment of travelers' diarrhea 550mg: Indicated for the reduction in recurrence of episodes of overt hepatic encephalopathy	Under Development
RIVAROXABAN (Xarelto®)	F.C. Tablets	2.5mg, 10mg, 15mg, 20mg	Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults	EU Approved
RISEDRONATE (Actonel®)	F.C. Tablets	5mg, 30mg, 35mg	Postmenopausal Osteoporosis Treatment and Paget's disease (30mg) Treatment of osteoporosis in men at high risk of fractures (35mg)	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
RIVASTIGMINE (Exelon®)	Hard capsules	1.5mg 3mg 4.5mg 6mg	Dementia of the Alzheimer type symptomatic treatment Treatment of dementia in patients with idiopathic Parkinson's disease	EU Approved
RIZATRIPTAN (Maxalt®)	Orodispersible tablets	5mg 10mg	Headache phase of migraine attacks acute treatment	EU Approved
RIZATRIPTAN (Maxalt®)	Tablets	5mg 10mg	Headache phase of migraine attacks acute treatment	EU Approved
ROPINIROLE (Requip®)	F.C. Tablets	0.25mg, 0.5mg, 1mg, 2mg, 5mg	Parkinson's disease treatment	EU Approved
ROPINIROLE SR (Requip XL®)	Prolonged-release tablets	2mg, 3mg, 4mg, 8mg	Parkinson's disease treatment	EU Approved
SEVELAMER CARBONATE (Renvela®)	F.C. Tablets	800mg	Hyperphosphatemia control	EU Approved
SEMAGLUTIDE (Ozempic®)	Solution for injection in pre-filled pen	Single dose: 0.25mg, 0.5mg, 1mg, 2mg, Dual dose: 0.25mg, 0.5mg 0.68mg/mL, 1.34mg/mL	Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise	Under development

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
SEMAGLUTIDE (Wegovy®)	solution for injection in pre-filled pen	0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg solution for injection in pre-filled pen-disposable autoinjector 0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg solution for injection in pre-filled pen-Flex Touch	Indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in overweight adults	Under development
SEMAGLUTIDE (Rybelsus®)	Tablets	3mg 7mg 14mg	Treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise	Under development
SITAGLIPTIN (Januvia®)	F.C. Tablets	25mg 50mg 100mg	Used in patients with type 2 diabetes to improve the control of blood glucose (sugar) levels	EU Approved
SITAGLIPTIN METFORMIN (Janumet®)	F.C. Tablets	50mg/1000mg 50mg/850mg	Used in patients with type 2 diabetes to improve the control of blood glucose (sugar) levels	EU Approved
TACROLIMUS SR (Envarsus®)	Prolonged-release tablets	0.75mg 1.0mg 4mg	Prophylaxis of trans-plant rejection in adult kidney or liver allograft recipients Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients	Under Development

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
TERIFLUNOMIDE (Aubagio®)	F.C. Tablets	14mg	Indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (MS)	EU Approved
TOLTERODINE (Detrusitol®)	F.C. Tablets	1mg 2mg	Urge incontinence and/or increased urinary frequency and urgency symptomatic treatment	EU Approved
TOLTERODINE SR (Detrusitol XR®)	Prolonged-release hard capsules	2mg 4mg	Urge incontinence and/or increased urinary frequency and urgency symptomatic treatment	EU Approved
TOPIRAMATE (Topamac®)	F.C. Tablets	25mg, 50mg, 100mg, 200mg	Epilepsy treatment Migraine headache prophylaxis	EU Approved
TRANDOLAPRIL (Gopten®)	Capsules	0.5mg, 1mg 2mg, 4mg	Mild or moderate hypertension Left ventricular dysfunction after acute myocardial infarction	EU Approved
VALGANCICLOVIR (Valcyte®)	F.C. Tablets	450mg	Cytomegalovirus (CMV) retinitis in adult patients with AIDS treatment CMV disease prevention in CMV-negative adults and children (aged from birth to 18 years) who have received a solid organ transplant from a CMV-positive donor	EU Approved

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	KEY INDICATION(S)	DOSSIER STATUS
VALACICLOVIR PAEDIATRIC	Powder for oral suspension	50mg/ml 200mg/ml	Indicated for Cold Sores (Herpes Labialis) & Chickenpox	EU Submitted
VENLAFAXINE (Efexor IR®)	IR tablets	37.5mg 50mg 75mg	Treatment and recurrence prevention for major depressive episodes generalized anxiety disorder, social anxiety disorder & panic disorder treatment	EU Approved
VENLAFAXINE (Efexor XR®)	Prolonged release hard capsules	37.5mg 75mg 150mg	Treatment and recurrence prevention for major depressive episodes generalized anxiety disorder, social anxiety disorder & panic disorder treatment	EU Approved
VILDAGLIPTIN (Galvus®)	Tablets	50mg	Treatment of type 2 diabetes mellitus	EU Approved
VILDAGLIPTIN + METFORMIN (Eucreas®)	F.C. Tablets	50/500mg 50/850mg 50/1000mg	Treatment of type 2 diabetes mellitus	EU Approved
VORICONAZOLE (Vfend®)	F.C. Tablets	50mg 200mg	Broad spectrum antifungal	EU Approved
VORICONAZOLE (Vfend®)	Powder for solution for infusion	200mg	Broad spectrum antifungal	EU Approved

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