



✚ Pharmathen

**2023**

**GLOBAL PRODUCT  
CATALOGUE**

# Table of contents

- 1. Company Profile**
- 2. Product Portfolio**
  - i. Long Acting Injectables**
  - ii. Ophthalmic formulations**
    - a) Preservative Free Ophthalmics in multi dose vials**
    - b) Preserved Ophthalmics in multi dose vials**
  - iii. Generic finished dosage**

## 1 Company Profile

We are one of the leading complex drug delivery and formulation developers, using our key in-house technologies to support improved patient compliance. We service a broad partner network of 250+ customers in 90+ countries throughout Europe, North America, South America, Middle East, Asia, Australasia and Southern Africa.

Our portfolio consists of over 100 products, and today we are working on one of the most extensive and advanced pipelines of Long Acting Injectables (LAI) and other complex injectables, Sustained Release Oral Solid and Ophthalmic formulations, both Preserved and Preservative free, produced in our US-FDA and EU-approved manufacturing facilities.

We have fully validated to commercial scale multiple LAI in each of the three major LAI technology platforms (Microspheres, Nanosuspensions and Nano-Gels), and have registered these products with regulatory authorities in multiple countries globally.

These platforms now support the enrichment of our pipeline with the addition of Long-Acting Therapeutic Technologies (LATT) which will target enhanced patient compliance for existing drug delivery therapies and methods, and support product Life Cycle Management (LCM) opportunities. In addition, through the utilization of these key technologies, we're offering B2B partnering solutions either for new drug candidates or your own LCM LATT candidates.

We proudly employ more than 1,300 people from over 22 different nationalities across 9 locations. Through our everyday activities and drug delivery advancements we remain committed to our vision "to make a difference in people's lives".





## 2 PRODUCT PORTFOLIO





# Long Acting Injectables

With the foundations 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	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
ARIPIRAZOLE	Long-acting Injectable Nanosuspension	300mg/vial 400mg/vial 300mg/syringe 400mg/syringe	Treatment of schizophrenia	Under Development
ARIPIRAZOLE LAUROXIL	Long-acting Injectable Nanosuspension	441mg/syringe 662mg/syringe 882mg/syringe 1064mg/syringe	Treatment of schizophrenia	Under Development
BUPRENORPHINE	Long-acting Injectable In situ depot (based on PLGA)	100mg/syringe 300mg/syringe	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine – containing product	Under Development
CABOTEGRAVIR RILPIVIRINE	Long-acting Injectable (2-drug co-packaged product) Suspension	400mg/600mg Kit: • single-dose vial of 400 mg/2 mL cabotegravir • single-dose vial of 600mg/2 mL rilpivirine 600mg/900mg Kit: • single-dose vial of 600 mg/3 mL cabotegravir • single-dose vial of 900 mg/3 mL rilpivirine	Treatment of patients with human immunodeficiency virus (HIV-1) infection	Under Development
EXENATIDE	Long-acting Injectable PLGA microparticles	2mg/auto-injector (BCise)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Under Development
LANREOTIDE	Long-acting Injectable Nano-gel	60mg/syringe 90mg/syringe 120mg/syringe	Long-term treatment of acromegaly; the treatment of patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	EU Approved





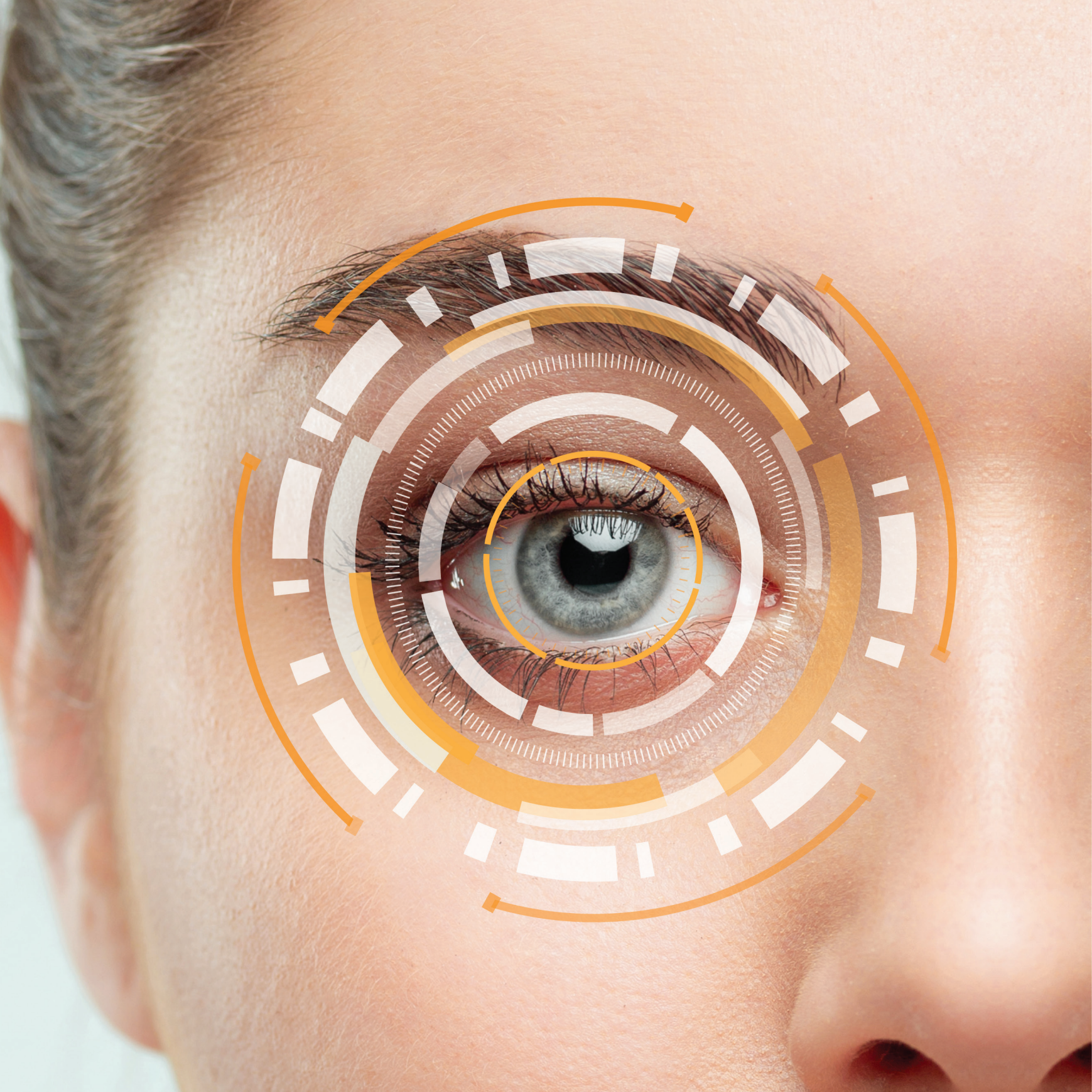
PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
LEUPROLIDE	Long-acting Injectable PLGA/PLA microparticle	Dual Chambered Syringe 3.75mg 7.5mg	Palliative treatment of advanced prostatic cancer, endometriosis and uterine leiomyomata (Fibroids)	Under Development
		Dual Chambered Syringe 11.25mg 22.5mg		
		Dual Chambered Syringe 30mg		
		Dual Chambered Syringe 45mg		
NALTREXONE	Long-acting Injectable PLGA microparticles	380mg/vial	Treatment of alcohol dependence; prevention of relapse to opioid dependence	US Approved
PALIPERIDONE PALMITATE 1M	Long-acting Injectable Nanosuspension	25mg/syringe 50mg/syringe 75mg/syringe 100mg/syringe 150mg/syringe	Treatment of schizophrenia in adult patients	EU Approved
PALIPERIDONE PALMITATE 3M	Long-acting Injectable Nanosuspension	175mg/syringe 263mg/syringe 350mg/syringe 525mg/syringe	Maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product	Under Development



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
PALIPERIDONE PALMITATE 6M	Long-acting Injectable Nanosuspension	700mg/syringe 1000mg/syringe	Maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly or 3-monthly paliperidone palmitate injectable products	Under Development
PASIREOTIDE	Long-acting Injectable PLGA microparticles	20mg/vial 40mg/vial 60mg/vial	Treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option (listed as an orphan indication in EU) Orphan indication in EU only: Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed	Under Development
RISPERIDONE	Long-acting Injectable PLGA microparticles	12.5mg/vial 25mg/vial 37.5mg/vial 50mg/vial	Acute and chronic schizophrenic psychoses treatment	EU Approved
TRIAMCINOLONE ACETONIDE	Long-acting Injectable PLGA microparticles	32mg/vial	An intra-articular injection for the management of osteoarthritis pain of the knee	Under Development







## **ii OPTHALMIC FORMULATIONS**





# ii. Ophthalmic Formulations

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



## a Preservative Free Ophthalmics in multi dose vials

PRODUCT	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
<b>BIMATOPROST PRESERVATIVE FREE</b>	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
<b>BIMATOPROST TIMOLOL PRESERVATIVE FREE</b>	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
<b>BRIMONIDINE PRESERVATIVE FREE</b>	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
<b>BRIMONIDINE TIMOLOL PRESERVATIVE FREE</b>	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	Dossier Ready
<b>BRINZOLAMIDE PRESERVATIVE FREE</b>	Eye drops suspension	10mg /ml	Indicated to decrease elevated intraocular pressure in ocular hypertension and open-angle glaucoma	Under Development



PRODUCT	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
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
CYCLOSPORINE PRESERVATIVE FREE	Ophthalmic emulsion	0,5mg/ml	Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca	Under Development
CYCLOSPORINE PRESERVATIVE FREE	Eye drops, emulsion	1mg/ml	Severe keratitis that has not improved despite treatment with tear substitutes in adults. Vernal keratoconjunctivitis (VKC) in children and adolescents	Under Development
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	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	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 glaucoma 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	Dossier Ready
LIFITEGRAST PRESERVATIVE FREE	Ophthalmic solution	50mg/ml	Lymphocyte function-associated antigen-1 (LFA-1) antagonist indicated for the treatment of the signs and symptoms of dry eye disease (DED)	Under Development





PRODUCT	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
TIMOLOL PRESERVATIVE FREE	Eye drops solution multi dose container	2.5mg/ml 5mg/ml	Elevated intraocular pressure decrease	EU Approved
TRAVOPROST PRESERVATIVE FREE	Eye drops solution multi dose container	40mcg/ml	Elevated intraocular pressure decrease	EU Approved
TRAVOPROST 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





## b Preserved ophthalmic finished formulations in multi dose vials

PRODUCT	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
BIMATOPROST	Eye drops solution	0.1mg/ml 0.3mg/ml	Reduction of elevated intraocular pressure in open-angle glaucoma or ocular hypertension	EU Approved
BRINZOLAMIDE	Eye drops, suspension	10mg/ml	Intraocular Pressure Elevation Treatment in Ocular Hypertension and in Open-angle Glaucoma	EU Approved
BRINZOLAMIDE BRIMONIDINE	Eye drops, suspension	10mg/ml 2mg/ml	Reduction of elevated intraocular pressure in open-angle glaucoma or ocular hypertension	Dossier Ready New
BRINZOLAMIDE TIMOLOL	Eye drops, suspension	10mg/ml 5mg/ml	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma	Dossier Ready New
DORZOLAMIDE	Eye drops solution	20mg/ml	Intraocular pressure elevation treatment	EU Approved

PRODUCT	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
DORZOLAMIDE TIMOLOL	Eye drops solution	20mg/ml 5mg/ml	Intraocular pressure elevation treatment	EU Approved
MOXIFLOXACIN	Eye drops solution	5mg/ml	Bacterial infections treatment	EU Approved
TRAVOPROST	Eye drops solution	40mcg/ml	Elevated intraocular pressure decrease	EU Approved
TRAVOPROST	Eye drops solution	30mcg/ml	Elevated intraocular pressure decrease	EU Approved
TRAVOPROST TIMOLOL	Eye drops solution	40mcg/ml 5mg/ml	Elevated intraocular pressure decrease	EU Approved







**iii GENERIC FINISHED DOSAGE**



## Generic finished dosage

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



PRODUCT	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
ALENDRONATE +CHOLECALCIFEROL	Tablets	70mg/2800IU 70mg/5600IU	Postmenopausal osteoporosis	EU Approved
APREMILAST	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	Under Development
APREPITANT	Injectable emulsion for intravenous use	130 mg	Indicated in adults, in combination with other antiemetic agents, for the prevention of: - acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high dose cisplatin - nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)	Under Development
APREPITANT	Hard capsules	40mg, 80mg, 125mg, 165mg	Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults	EU Approved





PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
ARIPIRAZOLE	Orodispersible tablets	10mg 15mg 30mg	Schizophrenia, manic episode treatment	EU Approved
ARIPIRAZOLE	Tablets	5mg 10mg 15mg 30mg	Schizophrenia, manic episode treatment	EU Approved
ATOMOXETINE	Hard capsules	10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg	Treatment of Attention-Deficit/ Hyperactivity Disorder (ADHD)	EU Approved
ATORVASTATIN	F.C. Tablets	10mg, 20mg 40mg, 80mg	Hypercholesterolemia treatment, cardiovascular disease prevention	EU Approved
CASPOFUNGIN	Powder for concentrate for solution for infusion	50mg 70mg	Invasive candidiasis, invasive aspergillosis treatment	EU Approved
CEFUROXIME AXETIL	F.C. Tablets	125mg 250mg 500mg	Mild to severe infections treatment	EU Approved
CIPROFLOXACIN	Solution for infusion	100mg/50ml 200mg/100ml 400mg/200ml	Infections treatment	EU Approved

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
CIPROFLOXACIN	F.C. Tablets	250mg 500mg 750mg	Infections treatment	EU Approved
CISATRACURIUM BESYLATE	Solution for injection	2mg/ml 5mg/ml	Adjunct to general anesthesia or sedation in the Intensive Care Unit (ICU) to relax skeletal muscles and to facilitate tracheal intubation and mechanical ventilation	EU Approved
CLOPIDOGREL	F.C. Tablets	75mg	Prevention of Atherothrombotic and Thromboembolic Events	EU Approved
DABIGATRAN	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)	Dossier Ready
DARUNAVIR	F.C. Tablets	75mg, 150mg, 300mg, 400mg, 600mg, 800mg	Treatment of patients with human immunodeficiency virus (HIV-1) infection	EU Approved



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
DEFERASIROX	Tablets	90mg 180mg 360mg	Treatment of chronic iron overload due to frequent blood transfusions	EU Approved
DIMENHYDRINATE	Sublingual tablets	50mg	Prevention and treatment of motion sickness. Symptomatic treatment of short duration of nausea and vomiting not accompanied with fever	EU Approved
DIMETHYL FUMARATE	Delayed release capsules	120mg 240mg	Treatment of adult patients with relapsing remitting multiple sclerosis	Available
DULAGLUTIDE	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	Hard gastro-resistant capsules	30mg 60mg	Treatment of depression and generalized anxiety disorder. Treatment of diabetic peripheral neuropathic pain	EU Approved
ENTECAVIR	F.C. Tablets	0.5mg 1mg	Treatment of chronic hepatitis B virus (HBV) infection	EU Approved

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
ELIGLUSTAT	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
EPLERENONE	F.C. Tablets	25mg 50mg	Beta-blockers therapy	EU Approved
ESCITALOPRAM	F.C. Tablets	5mg, 10mg, 15mg, 20mg	Major depressive episodes, Panic disorder, social anxiety disorder, generalized anxiety disorder and obsessive-compulsive disorder treatment	EU Approved
ESOMEPRAZOLE	Powder for solution for injection/infusion	40mg	Gastric antisecretory treatment for adults and children	EU Approved
FEBUXOSTAT	F.C. Tablets	80mg 120mg	Treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (80mg) Prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumor Lysis Syndrome (TLS) (120mg)	EU Approved





PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
FERRIC CARBOXYMALTOSE	Solution for injection/infusion	100mg/2ml 500mg/10ml 750mg/15ml 1.000mg/20ml	Treatment of iron deficiency	Under Development
FERUMOXYTOL	Injection for Intravenous (IV) use	30mg/ml (510 mg of elemental iron in 17 mL)	An iron replacement product indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD)	Under Development
FINASTERIDE	F.C. Tablets	5mg	Benign prostatic hyperplasia (BPH) treatment and control	EU Approved
FINGOLIMOD	Hard capsules	0.5mg	Indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis	EU Approved
FLUCONAZOLE	Solution for infusion	50mg/25ml 100mg/50ml 200mg/100ml 400mg/200ml	Anti-infective therapy	EU Approved
FLUCONAZOLE	Hard capsules	50mg, 100mg 150mg, 200mg	Anti-infective therapy	EU Approved

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
FLUVASTATIN XL	Prolonged release tablets	80mg	Dyslipidemia adjunct to diet & Secondary prevention in coronary heart disease	EU Approved
GALANTAMINE	F.C. Tablets	4mg 8mg 12mg	Dementia of the Alzheimer type symptomatic treatment	Dossier Ready
GALANTAMINE SR	Prolonged-release hard capsules	8mg 16mg 24mg	Dementia of the Alzheimer type symptomatic treatment	EU Approved
IBANDRONATE	Concentrate for solution for infusion	1mg/1ml 2mg/2ml 6mg/6ml	Prevention of Skeletal Events and Treatment of Hypercalcemia	EU Approved
IBANDRONATE	F.C. Tablets ONCE A MONTH	150mg	Postmenopausal osteoporosis treatment	EU Approved
IBANDRONATE	F.C. Tablets	50mg	Prevention of Skeletal Events in Patients with Cancer	EU Approved
ISOTRETINOIN	Soft gel capsules	5mg 10mg 20mg	Severe forms of acne treatment	EU Approved



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
IRON SUCROSE	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
IVABRADINE	F.C. Tablets	2.5mg 5mg 7.5mg	Treatment of chronic stable angina pectoris in coronary artery disease Treatment of chronic heart failure	EU Approved
LEFLUNOMIDE	F.C. Tablets	10mg, 15mg, 20mg, 100mg	Active rheumatoid arthritis treatment psoriatic arthritis treatment	EU Approved
LEVETIRACETAM	Concentrate for solution for infusion	100mg/ml	Epilepsy treatment	EU Approved
LEVETIRACETAM	Oral solution	100mg/ml	Epilepsy treatment	EU Approved
LEVETIRACETAM	F.C. Tablets	250mg, 500mg, 750mg, 1000mg	Epilepsy treatment	EU Approved

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
LEVOFLOXACIN	Solution for infusion	5mg/ml	Infections treatment	EU Approved
LEVOFLOXACIN	F.C. Tablets	250mg 500mg	Infections treatment	EU Approved
LINEZOLID	F.C. Tablets	600mg	Nosocomial and community acquired pneumonia, complicated skin and soft tissue infections treatment	EU Approved
LIRAGLUTIDE	Solution for injection in pre-filled pen	6mg/ml	Treatment of adults with 2 diabetes mellitus as an adjunct to diet and exercise	Dossier Ready Q3 2024
LIRAGLUTIDE	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 $\geq 30$ kg/m <sup>2</sup> (obesity), or $\geq 27$ kg/m <sup>2</sup> to $< 30$ kg/m <sup>2</sup> (overweight)	Under Development
LOSARTAN	F.C. Tablets	12.5mg, 25mg, 50mg, 100mg	Essential hypertension treatment	EU Approved





PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
LOSARTAN + HCTZ	F.C. Tablets	50/12.5mg 100/25mg	Essential hypertension treatment	EU Approved
MEMANTINE	F.C. Tablets	10mg 20mg	Moderate to Severe Alzheimer's Disease Treatment	EU Approved
MEROPENEM	Powder for solution for injection or infusion	500mg 1g	Infections treatment	EU Approved
MIRABEGRON	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	F.C. Tablets	10mg	Asthma treatment	EU Approved
MONTELUKAST	Chewable tablets	4mg 5mg	Asthma treatment	EU Approved

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
MOXIFLOXACIN	F.C. Tablets	400mg	Bacterial infections treatment	EU Approved
MOXIFLOXACIN	Solution for infusion	400mg / 250ml	Bacterial infections treatment	EU Approved
NETUPITANT PALONOSETRON	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	Solution for injection	12mg/5ml (2.4mg/ml)	Treatment of spinal muscular atrophy (SMA) in pediatric and adult patients	Under Development
OLANZAPINE	Orodispersible tablets	5mg 10mg 15mg 20mg	Treatment of Schizophrenia or Manic Episode bipolar disorder recurrence prevention (manic episode patients responding to therapy)	EU Approved



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
OLANZAPINE	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	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	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
ONDANSETRON	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
PALIPERIDONE	Prolonged-release tablets	1.5mg, 3mg, 6mg, 9mg, 12mg	Schizophrenia and Schizoaffective Disorder treatment	Under Development

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
PARICALCITOL	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	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)	F.C. Tablets	5mg 10mg	Prevention of atherothrombotic events in adult patients with acute coronary syndrome	Dossier Ready
PREGABALIN	Hard capsules	25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg	Neuropathic pain, epilepsy and generalized anxiety disorder treatment	EU Approved
QUETIAPINE SR	Prolonged-release tablets	50mg, 150mg, 200mg, 300mg, 400mg, 600mg	Schizophrenia and bipolar disorder treatment	EU Approved
RALOXIFENE	F.C. Tablets	60mg	Postmenopausal osteoporosis treatment and prevention	EU Approved





PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
RANOLAZINE	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	Dossier Ready
REPAGLINIDE	Tablets	0.5mg 1mg 2mg	Type 2 diabetes mellitus adjunct to diet	EU Approved
RIFAXIMIN	Tablets	200mg 550mg	200mg: Treatment of travelers' diarrhea 550mg: Indicated for the reduction in recurrence of episodes of overt hepatic encephalopathy	Dossier Ready Q1 2024
RIOCIGUAT	film-coated tablets	0.5mg 1mg 1.5mg 2mg 2.5mg	Treatment of Chronic thromboembolic pulmonary hypertension (CTEPH) and Pulmonary arterial hypertension (PAH)	Under Development
RIVAROXABAN	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	Dossier Ready

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
RISEDRONATE	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
RIVASTIGMINE	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	Orodispersible tablets	5mg 10mg	Headache phase of migraine attacks acute treatment	EU Approved
RIZATRIPTAN	Tablets	5mg 10mg	Headache phase of migraine attacks acute treatment	EU Approved
ROPINIROLE	F.C. Tablets	0.25mg 0.5mg 1mg 2mg 5mg	Parkinson's disease treatment	EU Approved
ROPINIROLE SR	Prolonged-release tablets	2mg, 3mg, 4mg, 8mg	Parkinson's disease treatment	EU Approved



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
ROPIVACAINE	Solution for infusion in bags 100ml, 200ml	2mg/ml	Surgical anesthesia and acute pain management	EU Approved
ROPIVACAINE	Solution for injection in vials 10ml, 20ml	2mg/ml 5mg/ml 7.5mg/ml 10mg/ml	Surgical anesthesia and acute pain management	EU Approved
SELEXIPAG	F.C. Tablets	200mcg 400mcg 600mcg 800mcg 1.000mcg 1.200mcg 1.400mcg 1.600mcg	Indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies	Under Development
SEVELAMER CARBONATE	F.C. Tablets	800mg	Hyperphosphatemia control	EU Approved
SEVELAMER CARBONATE CHEWABLE	Fast disintegrating chewable tablets	800mg	Control of serum phosphorous in patients with chronic kidney disease	Under Development

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
SEMAGLUTIDE	Solution for injection in pre-filled pen	Multi use/single dose pen: 0.25mg, 0.5mg & 1mg (1.34mg/mL) & 2mg (2.68mg/mL) Multi use/dual dose pen: 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
SEMAGLUTIDE	Solution for injection in pre-filled pen	Single use/single dose pen (Autoinjector): 0.25mg, 0.5mg, 1mg, 1.7mg & 2.4mg Multi use/single dose pen (Flex Touch): 0.25mg, 0.5mg, 1mg, 1.7mg & 2.4mg	Indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of $\geq 30$ kg/m <sup>2</sup> (obesity), or $\geq 27$ kg/m <sup>2</sup> to $< 30$ kg/m <sup>2</sup> (overweight)	Under Development
SEMAGLUTIDE	Tablets	3mg 7mg 14mg	Treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise	Under Development
SILDENAFIL	F.C. Tablets	25mg 50mg 100mg	Treatment of erectile dysfunction in adult males	EU Approved
SITAGLIPTIN	F.C. Tablets	25mg 50mg 100mg	Used in patients with type 2 diabetes to improve the control of blood glucose (sugar) levels	Dossier Ready





PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
SITAGLIPTIN METFORMIN	F.C. Tablets	50mg/1000mg 50mg/850mg	Used in patients with type 2 diabetes to improve the control of blood glucose (sugar) levels	Dossier Ready
TACROLIMUS CR	Prolonged-release hard capsules	0.5mg 1mg 3mg 5mg	Prophylaxis of transplant rejection in adult kidney or liver allograft recipients Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products	EU Approved
TAPENTADOL CR	Prolonged release tablets	50mg 100mg 150mg 200mg 250mg	Treatment of severe chronic pain in adults which can be adequately managed only with opioid analgesics	Dossier Ready
TERIFLUNOMIDE	F.C. Tablets	14mg	Indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (MS)	Dossier Ready
TOLTERODINE	F.C. Tablets	1mg 2mg	Urge incontinence and/or increased urinary frequency and urgency symptomatic treatment	EU Approved
TOLTERODINE SR	Prolonged-release hard capsules	2mg 4mg	Urge incontinence and/or increased urinary frequency and urgency symptomatic treatment	EU Approved

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
TOPIRAMATE	F.C. Tablets	25mg 50mg 100mg 200mg	Epilepsy treatment Migraine headache prophylaxis	EU Approved
TRANDOLAPRIL	Capsules	0.5mg 1mg 2mg 4mg	Mild or moderate hypertension Left ventricular dysfunction after acute myocardial infarction	EU Approved
VALACICLOVIR	F.C. Tablets	500mg	Herpes zoster, herpes simplex therapy & CMV infection prophylaxis	EU Approved
VALGANCICLOVIR	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
VALACICLOVIR PAEDIATRIC	Powder for oral suspension	50mg/ml 200mg/ml	Indicated for Cold Sores (Herpes Labialis) & Chickenpox	Dossier Ready Q2 2024



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
VENLAFAXINE	IR tablets	37.5mg 50mg 75mg	Treatment and recurrence prevention for major depressive episodes generalized anxiety disorder, social anxiety disorder and panic disorder treatment	EU Approved
VENLAFAXINE	Prolonged release hard capsules	37.5mg 75mg 50mg	Treatment and recurrence prevention for major depressive episodes generalized anxiety disorder, social anxiety disorder and panic disorder treatment	EU Approved
VILDAGLIPTIN	Tablets	50mg	Treatment of type 2 diabetes mellitus	EU Approved
VILDAGLIPTIN + METFORMIN	F.C. Tablets	50/500mg 50/850mg 50/1000mg	Treatment of type 2 diabetes mellitus	EU Approved
VORICONAZOLE	F.C. Tablets	50mg 200mg	Broad spectrum antifungal	EU Approved
VORICONAZOLE	Powder for solution for infusion	200mg	Broad spectrum antifungal	EU Approved

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