



PRODUCT LIST

2024

GENERICs FDFs

Available Dossiers

Dossiers Under Development

Dossiers Under Consideration

GENERICs APIs

Available Portfolio - Malta

Available Portfolio - Spain

Under Development

Under Consideration

CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

FDFs

Biocide Grade

Pharmaceutical Grade

Cosmetic Grade





AVAILABLE DOSSIERS

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
Apixaban	Film-coated tablets	2,5 mg, 5 mg	Eliquis® BMS/Pfizer	Stroke and systemic embolism Deep vein and thrombosis Pulmonary embolism	Approved: CIS, EU, UK, US, SW, TH Filed: IL
Captopril	Tablets	12,5 mg, 25 mg, 50 mg, 100 mg	Captopril Mylan	Hypertension Heart failure	Approved: US
Daptomycin	Powder for solution for injection or infusion in glass vial	350 mg, 500 mg	Cubicin® Merck	Skin and soft-tissue infections Endocarditis	Approved: CA, EU, UK, KR, UA, AU, ZA
Mirtazapine	Tablets	7,5 mg*, 15 mg, 30 mg, 45 mg	Remeron® Organon	Major depression	Approved: EU, US
Prucalopride Succinate	Film-coated tablets	1 mg, 2 mg	Motegrity® Shire Resolor® Takeda	Chronic constipation	Approved: EU, UK Filed: MENA, US
Rivaroxaban	Film-coated tablets	2,5 mg, 10 mg, 15 mg, 20 mg	Xarelto® Bayer	Stroke and systemic embolism Deep vein thrombosis Pulmonary embolism	Approved: EU, FWA, IQ Filed: ESA, MX
Sugammadex Sodium	Solution for injection	200 mg / 2 ml 500 mg / 5 ml	Bridion® MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU, EC, HN, IL, UK, MX, NZ Filed: CA, KSA, PH, UAE, VN
Sunitinib Maleate	Capsules	12,5 mg, 25 mg, 37,5 mg, 50 mg	Sutent® Pfizer	Renal carcinoma Pancreatic and stromal tumors	Approved: EU, KSA, PE Filed: JO, MX, PE
Thalidomide	Capsules	50 mg	Thalidomid Celgene® Celgene	Multiple myeloma	Approved: EU, UK
Tobramycin	Nebulizer solution in plastic ampoule blow-fill-seal	300 mg / 5 ml	Tobi® Novartis	Cystic fibrosis	Approved: AU, EU, UK, BR, PA, GT, NZ, US, KSA Filed: AE, JO
Varenicline L-tartrate	Tablets	0,5 mg, 1 mg	Chantix®, Champix® Pfizer	Smoking cessation	Approved: AU, EU Filed: US



DOSSIERS UNDER DEVELOPMENT

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
Solid Dosage Form:					
Fluvoxamine CR	Capsules extended release	100 and 150 mg	Luvox CR® Jazz Pharmaceuticals	Obsessive compulsive disorder	Q2 2025
Ivacaftor	Film coated tablets	150 mg	Kalydeco® Vertex	Cystic fibrosis	Q3 2025
Lofexidine	Film coated tablets	0,18 mg	Lucemyra® US WorldMeds	Opioid withdrawal	Q4 2024
Ruxolitinib Hemifumarate	Tablets	5 mg, 10 mg, 15 mg, 20 mg	Jakavi® (EU) Novartis Europharm / Incyte	Myelofibrosis Polycythemia vera Graft-versus-host disease (GvHD)	Q3 2024
Voclosporin	Soft gel capsules	7,9 mg	Lupkynis® Aurinia Pharmaceuticals / Otsuka Pharmaceutical	Lupus Nephritis	Q1 2025 (NCE-1)
Liquid Dosage Form:					
Calcium Gluconate	Intravenous plastic vials	100 mg/ml	Calcium gluconate® Fresenius Kabi	Treatment of acute symptomatic hypocalcemia	Q1 2026
Esmolol	Ready-to-use plastic bags	10 mg/ml 20 mg/ml	Brevibloc® in plastic container Baxter	Supraventricular tachycardia or non-compensatory sinus tachycardia, intraoperative and postoperative tachycardia and hypertension	Q4 2025
Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic	Intravenous plastic vial	236 mg/mL + 224 mg/mL	POTASSIUM PHOSPHATES®, Fresenius Kabi	Phosphorus replacement indicated as a source of phosphorus in intravenous fluids to correct hypophosphatemia and for parenteral nutrition	Q1 2026
Sodium Phosphate, Dibasic, Heptahydrate; Sodium Phosphate, Monobasic, Anhydrous	Intravenous plastic vial	142 mg/mL + 276 mg/mL	SODIUM PHOSPHATES®, Hospira	Source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia. Also used as an additive for parenteral fluid	Q1 2026
Revefenacin	Solution for inhalation	175 mcg / 3 ml	Yupelri® Mylan	Chronic obstructive pulmonary disease (COPD)	Already submitted on NCE-1 (Nov 22)
Innovation:					
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Bipolar disorders	2028



DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
Solid Dosage Form:				
⬡ Elacestrant	Film-coated tablets	86 mg and 345 mg	Orserdu [®] Stemline Therapeutics	Breast cancer
⬡ Ivacaftor + Tezacaftor	Film-coated tablets	150/100 mg & 75/50 mg	Symdeko [®] (US) and Symkevi [®] (EU) Vertex	Cystic fibrosis
⬡ Ivacaftor + Tezacaftor + Elexacaftor	Film-coated tablets	75/50/100 mg & 37.5/25/50 mg	Trikafta [®] (US) and Kaftrio [®] (EU) Vertex	Cystic fibrosis
Suvorexant	Tablet	5 mg, 10 mg, 15 mg & 20 mg	Belsomra [®] Merck & Co	Treatment of insomnia
Liquid Dosage Form:				
Aprepitant	Vial	7,2 mg/mL	Aponvie [®] Heron Therapeutics	Nausea or Vomiting
Cangrelor	Intravenous powder (vial)	50 mg/mL	Kengreal [®] (US) and Kengrexal [®] (EU) Chiesi	Adjunct to percutaneous coronary intervention
Casimersen	Vial	50 mg/mL	Amondys 45 [®] Sarepta	Duchenne muscular dystrophy
Cupric Sulfate + Manganese Sulfate + Selenious Acid + Zinc Sulfate	Vial	0.3mg/ml (cupric sulfate) + 55mcg/ml (manganese sulfate) + 60mcg/ml (selenious acid) + 3mg/ml (Zinc sulfate)	Tralement [®] , AM Reagent	Source of zinc, copper, manganese, and selenium
Etelcalcetide	Vial	5 mg/mL	Parsabiv [®] Amgen	Secondary hyperparathyroidism
Ferumoxylol	Vial	30 mg/ml	Feraheme [®] AMAG	Cardiovascular anemia
Inclisiran	Pre-filled syringes	189 mg/mL	Leqvio [®] Novartis	Primary hyperlipidemia
Isavuconazonium Sulfate	Intravenous powder (vial)	372 mg	Cresemba [®] Astellas	Invasive aspergillosis & mucormycosis
Trilaciclib	Intravenous powder (vial)	300 mg/mL	Cosela [®] G1 Therapeutics / Boehringer Ingelheim	Chemotherapy-induced bone marrow suppression
Topical Dosage Form:				
⬡ Ruxolitinib Phosphate	Cream	1.5%	Opzelura [®] Incyte	Atopic dermatitis and vitiligo
Innovation:				
High-dose oncological	Film-coated tablets	400 mg	NA	Leukemia



AVAILABLE PORTFOLIO - MALTA






Apixaban	Micafungin Sodium	Rivaroxaban
Desvenlafaxine Succinate	Prucalopride	Sugammadex Sodium
Edaravone	Rasagiline Tartrate	Sunitinib Malate
Lofexidine	Revefenacin	

AVAILABLE PORTFOLIO - SPAIN

Adapalene	Fluvoxamine Maleate	Nepafenac [sterile and non sterile]
Brimonidine Tartrate	Guanfacine HCl	Olopatadine HCl
Captopril	Lamotrigine	Paroxetine HCl
Cinacalcet HCl	Loxapine Base	Pazopanib
Cyclobenzaprine HCl	Loxapine Succinate	Pimecrolimus
Desvenlafaxine Base	Mexiletine HCl	Quetiapine Fumarate
Felodipine	Mirtazapine	Rivaroxaban
		Varenicline L-tartrate



UNDER DEVELOPMENT

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DMF READINESS
Elacestrant	Orserdu® Stemline Therapeutics	Metastatic breast cancer	Q3 2026
 Ivacaftor	Kalydeco® Vertex	Cystic fibrosis	Q4 2024
Opicapone	Ongentys® Bial and Neurocrine Biosciences	“Off” episodes in Parkinson	Q4 2024
Relugolix	Orgovyx®, Myfembree® (US) / Ryeqo® (EU), Myovant Sciences	Prostate cancer and uterine fibroid bleeding Pain associated with endometriosis	Q2 2024
 Ruxolitinib Hemifumarate	Jakavi®, Novartis	Myelofibrosis, polycythemia vera and graft-versus-host-disease	Q3 2024
 Ruxolitinib Phosphate	Jakafi®, Novartis	Myelofibrosis, polycythemia vera Graft-versus-host-disease	Q3 2025
Sitagliptin	Januvia® / Janument® / Janumet XR®, Merck & Co	Type 2 diabetes mellitus	Q3 2026
 Tezacaftor	Symdeko® (US) and Symkevi® (EU) Vertex	Cystic fibrosis	Q1 2027
 Voclosporin	Lupkynis® Aurinia Pharmaceuticals and Otsuka Pharmaceutical	Lupus Nephritis	US DMF filed



UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION
Deucravacitinib	Sotyktu® Bristol-Myers Squibb	Plaque psoriasis
Elexacaftor	Trikafta® (US) and Kaftrio® (EU) Vertex	Cystic fibrosis
Fezolinetant	Veozah® Astellas	Vasomotor symptoms due to menopause
Venetoclax	Venclexta®, Abbvie	Leukemia





CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

API - ANTISEPTICS - AVAILABLE

Chlorhexidine Base		Chlorhexidine Diacetate	CEP
Chlorhexidine Digluconate 20% Solution	CEP	Chlorhexidine Dihydrochloride	CEP
Octenidine Dihydrochloride	DMF		

FDFs - BIOCIDES GRADE

CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	
Hydroalcoholic solution Transparent and coloured	2%	Plastic bottles	60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml More formats on request
	0,50%		
Aqueous solution	2%	Blow-fill-seal ampoules and plastic bottles	Single dose (10 ml), 60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml 10 ml, 60 ml, 75 ml
	0,50%		
Wipes Aqueous	2%	Individual sachet	20 x 20 cm, 6 x 7 cm
		Flow pack of 8 wipes	
Alcoholic		Individual sachet	
Hand scrub Transparent	4%	HDPE bottles with dosing pump	20 ml, 500 ml, 1000 ml



CHLORHEXIDINE AND OTHER ANTISEPTICS

FDFs - PHARMACEUTICAL GRADE

CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	REFERENCE PRODUCT	DOSSIER READINESS
Hydroalcoholic solution Transparent	2%	Plastic bottles 30 ml, 100 ml, 250 ml More formats on request		Submitted Q3 2023
Hydroalcoholic solution Transparent	0,50%	Plastic bottles 30 ml, 100 ml, 250 ml More formats on request		Approved: NL

CHLORHEXIDINE DIGLUCONATE - UNDER DEVELOPMENT DOSSIER

PRODUCT	STRENGTH	FORMATS AVAILABLE	REFERENCE PRODUCT	DOSSIER READINESS
Hydroalcoholic solution Coloured	2%	Plastic bottles 30 ml, 100 ml, 250 ml More formats on request		
Hydroalcoholic solution Coloured	0,50%	Plastic bottles 30 ml, 100 ml, 250 ml More formats on request		

OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	REFERENCE PRODUCT	DOSSIER READINESS
Combination of two active ingredients	TBD	Gel	NA	2028



CHLORHEXIDINE AND OTHER ANTISEPTICS

FDFs - COSMETIC GRADE

OCTENIDINE DIHYDROCHLORIDE - AVAILABLE DOSSIERS

PRODUCT		FORMATS AVAILABLE		INDICATION	DOSSIER READINESS
Cream		Bottle with pump biodegradable	500 ml	Coadyudant for atopic dermatitis	Product file ready for notification
Spray	2% phenoxyethanol + 0,1% octenidine	Plastic bottles	50 ml, 250 ml and 1.000 ml	Octenisept®	Submitted (Feb 2024)





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