



# PRODUCT LIST

2024

 **GENERICS FDFs**

Available Dossiers

Dossiers Under Development

Dossiers Under Consideration

 **GENERICS APIs**

Available Portfolio - Malta

Available Portfolio - Spain

Under Development

 **CHLORHEXIDINE AND OTHER ANTISEPTICS**

APIs

FDFs

Biocide Grade

Pharmaceutical Grade

Cosmetic Grade





## AVAILABLE DOSSIERS

MOLECULE	PHARMACEUTICAL FORM & STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER STATUS
Apixaban	Film-coated tablets 2,5 mg, 5 mg	Eliquis® BMS/Pfizer	Stroke and systemic embolism Deep vein and thrombosis Pulmonary embolism	Approved: US, EU, UK
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: 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, CIS, IL
Sugammadex Sodium	Solution for injection 200 mg / 2 ml 500 mg / 5 ml	Bridion® MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU, IL, UK, MX, NZ Filed: CA, SEA
Sunitinib Maleate	Capsules 12,5 mg, 25 mg, 37,5 mg, 50 mg	Sutent® Pfizer	Renal carcinoma Pancreatic and stromal tumors	Approved: EU, KSA Filed: MX, JO
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: JO, AE
Varenicline L-tartrate	Tablets 0,5 mg, 1 mg	Chantix®, Champix® Pfizer	Smoking cessation	Approved: AUS Filed: US



## DOSSIERS UNDER DEVELOPMENT

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
Calcium gluconate	Intravenous plastic vials	100 mg/ml	Calcium gluconate® Fresenius Kabi	Treatment of acute symptomatic hypocalcemia	Q1 2026
CNS long acting injectable	Subcutaneous or intramuscular injection	TBD	NA	Schizophrenia	
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	Q1 2026
Fluvoxamine CR	Capsules extended release	100 and 150 mg	Luvox CR® Jazz Pharmaceuticals	Obsessive compulsive disorder	Q1 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
Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic	Intravenous plastic vial	224 mg/mL + 236 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	276 mg/mL + 142 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)
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)



## DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
Aprepitant	Vials		Brand Company Aponvie® /Heron Therapeutics	Nausea or Vomiting
Aripiprazole lauroxil	Pre-filled syringes		Aristada®/Alkermes	Schizophrenia
Casimersen	Vials		Amondys 45® Sarepta	Duchenne muscular dystrophy
Dalbavancin	Vials		Dalvance® Durata Therapeutics/ Allergan/AbbVie	Skin Infections
Difelikefalin	Vials		Korsuva® Cara Therapeutics	Chronic kidney disease-associated pruritus and pain
Ferumoxytol	Vials		Feraheme® AMAG Pharmaceuticals	Cardiovascular Anemia
Inclisiran	Pre-filled syringes		Leqvio® The Medicines Company/ Novartis/ Alnylam Pharmaceuticals	Dyslipidemia
Isavuconazonium sulfate	Intravenous powder (vial)	372 mg	Cresemba® Astellas	Invasive aspergillosis mucormycosis
Lurbinectedin	Intravenous powder (vial)	4 mg	Zepzelca® PharmaMar / Jazz Pharmaceutical	Metastatic small cell lung cancer
Ruxolitinib Phosphate	Cream	1,5%	Opzelura® Incyte	Atopic dermatitis and vitiligo
Trabectedin	Intravenous powder (vial)	1 mg (US/EU), 0,25 mg (EU)	Yondelis® PharmaMar / Janssen	Unresectable or metastatic liposarcoma or leiomyosarcoma
Trilaciclib	Vials		Cosela® G1 Therapeutics / Boehringer Ingelheim	Organ Diseases



## AVAILABLE PORTFOLIO - MALTA





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

## AVAILABLE PORTFOLIO - SPAIN

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



## UNDER DEVELOPMENT

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DMF READINESS
 Ivacaftor	Kalydeco® Vertex	Cystic fibrosis	DMF Q4 2024
Opicapone	Ongentys® Bial and Neurocrine Biosciences	“Off” episodes in Parkinson	DMF Q4 2024
Relugolix	Orgovyx®, Myfembree® (US) / RYEQO (EU), Myovant Sciences	Prostate cancer and uterine fibroid bleeding Pain associated with endometriosis	DMF Q2 2024
 Ruxolitinib hemifumarate	Jakavi®, Novartis	Myelofibrosis, polycythemia vera and graft-versus-host-disease	DMF Q3 2024
 Ruxolitinib phosphate	Jakafi®, Novartis	Myelofibrosis, polycythemia vera Graft-versus-host-disease	DMF Q3 2025
Tezacaftor	Symdeko® (US) and Symkevi® (EU) Vertex	Cystic fibrosis	DMF Q1 2027
 Voclosporin	Lupkynis® Aurinia Pharmaceuticals and Otsuka Pharmaceutical	Lupus Nephritis	DMF Q2 2024





## UNDER CONSIDERATION

ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION
Amikacin	Arikayce kit® Insmed/PARI Pharma	Mycobacterium avium complex lung disease
Buprenorphine	Brixadi®, Butrans® and Sublocade® Braeburn, Purdue Pharma and Indivior	Opioid use disorder and pain management
Cenobamate	Xcopri® (US) and Ontozry® (EU) SK Biopharmaceuticals (US) and Angelini (EU)	Partial-onset seizures
Elexacaftor	Trikafta® (US) and Kaftrio® (EU) Vertex	Cystic fibrosis
Encorafenib	Braftovi® Array (US) and Pierre Fabre (EU)	Unresectable or metastatic melanoma and metastatic colorectal cancer
Levoketoconazole	Recorlev® Strongbridge	Endogenous hypercortisolemia in adults with Cushing's syndrome
Lumacaftor	Orkambi® Vertex	Cystic fibrosis
Lorlatinib	Lorbrena® (US) and Lorviqua® (EU) Pfizer	Metastatic non-small cell lung cancer
Lumateperone tosylate	Caplyta® Intra-Cellular Therapies and Bristol Myers Squibb	Schizophrenia and depressive episodes associated with bipolar disorders
Naltrexone	Vivitrol® Alkermes	Alcohol and opioid dependence
Naloxone hydrochloride	Kloxxado®, Narcan® Rextovy®, Rivive® Hikma, Emergent, Amphastar Pharms, Harm reduction therap	Opioid overdose
Potassium phosphates	Potassium phosphates®	Source of phosphorous when oral or enteral replacement is not possible, insufficient or contraindicated
Rimegepant sulphate	Nurtec® ODT (US) and Vydura® (EU) Pfizer and Biohaven	Migraine
Sodium phosphates	Sodium phosphates®, Hospira	Correction or prevention of hypophosphatemia in patients with restricted or no oral intake
Vibegron	Gemtesa® Urovant	Overactive bladder
Zanubrutinib	Brukinsa® BeiGene	Mantle cell lymphoma, Waldenström's macroglobulinemia, refractory marginal zone mymphoma, chronic lymphocytic leukemia and small lymphocytic lymphoma





# 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	
<b>Hydroalcoholic solution</b> Transparent and coloured	2%	Plastic bottles	60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml More formats on request
	0,50%		
<b>Aqueous solution</b>	2%	Blow-fill-seal ampoules and plastic bottles	Single dose (10 ml), 60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml
	0,50%		10 ml, 60 ml, 75 ml
<b>Wipes</b> Aqueous	2%	Individual sachet	20 x 20 cm, 6 x 7 cm
		Flow pack of 8 wipes	
Alcoholic		Individual sachet	
<b>Hand scrub</b> 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	
Hydroalcoholic solution Coloured	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request
Hydroalcoholic solution Transparent	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request

### CHLORHEXIDINE DIGLUCONATE - UNDER DEVELOPMENT DOSSIER

PRODUCT	STRENGTH	FORMATS AVAILABLE	
Hydroalcoholic solution Transparent and coloured	2%	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
 Spray	2% phenoxyethanol + 0,1% octenidine	Plastic bottles	50 ml, 250 ml and 1.000 ml	Octenisept®	Q1 2024
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





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